

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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ABU DHABI INVESTMENT AUTHORITY,	:	Civil Action No. 1:20-cv-01342
	:	
Plaintiff,	:	COMPLAINT FOR VIOLATIONS OF
	:	FEDERAL SECURITIES LAWS
vs.	:	
	:	
MYLAN N.V. and MYLAN INC.,	:	
	:	
Defendants.	:	
_____	X	<u>DEMAND FOR JURY TRIAL</u>

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Abu Dhabi Investment Authority (“Plaintiff”), by the undersigned attorneys, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and on information and belief as to all other matters based on the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission (“SEC”) filings made by Mylan N.V. and Mylan Inc. (together, “Mylan” or the “Company”), Mylan’s public documents, conference calls and announcements made by Mylan, wire and press releases published by and regarding Mylan, analysts’ reports and advisories about Mylan, government investigations and reports, information obtainable on the Internet, civil and regulatory complaints and court filings, drug pricing and market share information from proprietary databases, and consultation with industry experts. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## **I. INTRODUCTION**

1. Plaintiff brings this action under the Securities Exchange Act of 1934 (the “Exchange Act”) against Mylan to recover damages for losses Plaintiff suffered in connection with its acquisition of Mylan securities between February 21, 2012 and May 24, 2019, both dates inclusive (the “Relevant Period”). Plaintiff purchased or otherwise acquired Mylan securities at artificially inflated prices during the Relevant Period and suffered damages as a result of the violations of the securities laws alleged herein.

2. Mylan, together with its subsidiaries, develops, licenses, manufactures, markets, and distributes brand-name and generic pharmaceuticals worldwide. Mylan manufactures and sells, among other products, the EpiPen Auto-Injector® and EpiPen Jr Auto-Injector® (collectively, the “EpiPen”), a branded drug that allows the user to auto inject a measured dose of epinephrine to treat anaphylaxis, a life-threatening emergency to which one in thirteen children is susceptible. Mylan also manufactures and sells the following generic drugs, among others: albuterol sulfate, used to



treat asthma and other lung conditions; benazepril, used to treat high blood pressure; clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness; divalproex, used to treat certain types of seizures and migraines; doxycycline hyclate delayed release (“Doxy DR”), a tetracycline antibiotic used to treat a wide range of bacterial infections, including severe respiratory infections and anthrax; and propranolol, a beta-blocker used to treat and prevent heart attacks and other heart and circulatory conditions.

3. Mylan is a dishonest company. Over the past two decades, in over a dozen matters, Mylan has been repeatedly investigated by the Federal Trade Commission (“FTC”), the Department of Justice (“DOJ”), and the SEC, and sued by private litigants for fraudulently overcharging Medicaid for its drug purchases, for illegal price manipulation, for entering into illegal anticompetitive agreements, and for other wrongful conduct. These wrongs by Mylan are chronic – Mylan has repeated the same misdeeds time and again. And while the wrongs addressed in this complaint are only the most recent examples of Mylan’s proven history of such misdeeds, they are perhaps the most serious. Through the conduct described in this complaint, Mylan made lifesaving drugs less available to children, the elderly, and other ordinary Americans who struggle to afford these drugs.

4. Plaintiff brings this action because, during the Relevant Period, Mylan misled Plaintiff about a course of conduct intended to cheat Medicaid (the United States’ low-income healthcare program) out of its rightful rebates for EpiPen purchases; about anticompetitive conduct it engaged in to exclude competition, which allowed Mylan to inflate the price of the EpiPen astronomically beyond the reach of many consumers; and about a scheme to inflate the prices of critical generic drugs by over 1000% by engaging in numerous anticompetitive activities. In particular: (1) Mylan systematically and knowingly misclassified the EpiPen as a generic drug in

order to overcharge Medicaid by hundreds of millions of dollars for its purchases of this life-saving device for Medicaid recipients; (2) Mylan entered into exclusive arrangements with commercial insurance companies and pharmaceutical benefits managers in order to prevent competitor Sanofi-Aventis U.S. LLC (“Sanofi”) from successfully introducing a product to compete with the EpiPen; and (3) Mylan entered into, and maintained, anticompetitive agreements with its “competitors” to allocate the market and fix the prices for virtually all of its generic drugs, including, but not limited to, Doxy DR, fenofibrate, clonidine-TTS Patch, tolterodine extended release, capecitabine, enalapril, valsartan HCTZ, albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine, methotrexate, nadolol, tizanidine, trifluoperazine HCL, budesonide DR, buspirone hydrochloride, cimetidine tablets, diclofenac potassium, diltiazem HCL, estradiol, fluoxetine HCL, flurbiprofen, fluvastatin sodium, haloperidol, ketoconazole, ketoprofen, nitrofurantoin MAC capsules, pentoxifylline, prazosin HCL, prochlorperazine, tamoxifen citrate, and tolmetin sodium.

5. ***First***, as soon as Mylan acquired the rights to market the EpiPen, Mylan knowingly misclassified the EpiPen for the purposes of the Medicaid Drug Rebate Program (“MDRP”). Under the MDRP, drug companies enter into a contract with the agency that administers Medicaid, the Centers for Medicare & Medicaid Services (“CMS”), under which they agree to give CMS rebates on their drugs – rebates that represent bulk discounts on CMS’s massive drug purchases for Medicaid. Federal law requires that companies give Medicaid a lower rebate for generic drugs, which drug companies already sell at close to cost, than for brand-name or patented drugs, which drug companies usually sell at a significant markup. The responsibility of categorizing drugs correctly as generic or brand-name drugs lies with the drug companies.

6. This categorization is remarkably straightforward and follows unambiguously from laws and regulations that have remained essentially unchanged since 1990, when the MDRP was first implemented – if the Food and Drug Administration (“FDA”) approves a drug under a new drug application (“NDA”) (which is used for new, usually patented drugs), that drug is a brand-name drug for the purposes of the MDRP, and if the drug was not approved under an NDA, the drug is a generic drug.

7. There is not, and never has been, any question about how the EpiPen should be classified. Even a layperson wholly unfamiliar with laws and regulations regarding classification of the EpiPen would know that the EpiPen is a brand-name drug and not a generic – it is an extremely expensive, branded and patented product that bears a trademarked logo rather than an active ingredient on its label – it is nothing like the cheap generic medications Congress expected to be sold at close to cost. But just as importantly, a layperson also would have no trouble classifying the drug under Medicaid’s laws and regulations – all he or she would need to do is look up the EpiPen on the FDA’s website and note that it was approved under an NDA in order to classify the drug as a brand-name drug for the purposes of the MDRP. No exceptions to this rule existed in the laws and regulations governing classification of drugs for the purposes of the MDRP.

8. Mylan is not a layperson; rather, Mylan has an army of highly sophisticated lawyers. These lawyers were capable of doing what a layperson could do – of classifying the EpiPen correctly as a brand-name drug. Instead, Mylan knowingly misclassified the EpiPen as a generic drug from the time it first acquired the rights to the drug in 2007 to the present.

9. Indeed, before the Relevant Period, CMS expressly notified Mylan that the EpiPen was misclassified, as the Acting Administrator, Andrew M. Slavitt, has confirmed in correspondence with the U.S. Senate. In early 2009, the Inspector General of the Department of Health and Human

Services expressly told CMS that the EpiPen was misclassified for the purposes of the MDRP. Thereafter, on multiple occasions, CMS expressly notified Mylan that the EpiPen was misclassified. As Slavitt stated in an October 5, 2016 letter to Senator Ron Wyden, “CMS has, on multiple occasions . . . expressly told Mylan that the product [EpiPen] is incorrectly classified.” As detailed below, the most reasonable inference to be drawn about the timing of this notification is that CMS was not completely derelict in its duties and notified Mylan of this misclassification within three years at the latest upon receiving notice from the Inspector General.

10. Mylan repeatedly misrepresented to investors the legal situation it faced as a result of its blatant misclassification of the EpiPen for the purposes of the MDRP. In its SEC filings, Mylan repeatedly created the misimpression that the classification scheme for the purposes of the MDRP was highly complex, involved subjective judgments, and contained ambiguities. In fact, as Mylan admitted in other sections of its SEC filings, the classification scheme was simple and consisted of bright-line rules. Mylan created this misimpression because it knew, or recklessly disregarded, that its classification of the EpiPen was simply wrong.

11. Separately, Mylan also repeatedly misrepresented that there was no investigation into its classification of the EpiPen when, in fact, the DOJ had launched just such an investigation in November 2014. Mylan is independently liable for these misrepresentations.

12. **Second**, Mylan also engaged in anticompetitive conduct during the Relevant Period in an attempt to prevent competition for the EpiPen. In 2013, Mylan’s competitor, Sanofi, introduced a product, the Auvi-Q, to compete with the EpiPen in the market for epinephrine auto-injectors. The Auvi-Q was a superior product to the EpiPen in multiple ways: the product was designed to be flat and rectangular, so it would fit easily in purses and other places a smart-phone might fit, and the product included audible instructions that allowed users to operate the device in an emergency

without having to focus on reading the directions. In response to this competitive threat, Mylan began to offer unprecedented rebates of 30% or more on the cost of the EpiPen to third-party payors, including commercial insurance companies and pharmaceutical benefits managers.

13. As a result of its anticompetitive conduct, Mylan successfully blocked the Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine auto-injectors. In certain states where Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market.

14. Mylan repeatedly failed to tell the whole truth about the ways in which it competed and about the reasons for its financial success, including in the market for epinephrine auto-injectors, by failing to disclose this anticompetitive conduct. While Mylan's conduct certainly violated U.S. antitrust laws, including §2 of the Sherman Antitrust Act, investors cared about this conduct due to the significant liability to which it exposed Mylan.

15. *Third*, beginning in 2012 and continuing into the present, Mylan entered into anticompetitive agreements with its competitors in the generic drug market to allocate the market for, and to fix the prices of, the generic drugs they sold. For many years, the generic pharmaceutical industry, and Mylan as a key member of that industry, operated pursuant to an understanding among generic manufacturers not to compete with each other and to instead settle for what these competitors referred to as a "fair share." This understanding has permeated every segment of the industry – it covers not merely a select few drugs, but rather the entirety of Mylan's generic drug business. The purpose of the agreement is to avoid competition among generic manufacturers that would normally result in significant price erosion and great savings to the ultimate consumer. Rather than enter a particular generic drug market by competing on price in order to gain market share, competitors in the generic drug industry, including Mylan, systematically and routinely

communicate with one another directly, divvying up customers to create an artificial equilibrium in the market and maintain anticompetitive high prices. This “fair share” understanding was not the result of independent decision-making by individual companies to avoid competing with one another. Rather, it was a direct result of specific discussion, negotiation, and collusion among virtually all industry participants, led in part by Mylan, over the course of many years.

16. By 2012, unsatisfied with the mere avoidance of price erosion, Mylan and its co-conspirators embarked on one of the most egregious and damaging price-fixing conspiracies in the history of the United States. Mylan and its competitors sought to leverage the collusive nature of the industry to not only maintain their “fair share” of each generic drug market, but also to significantly raise prices on as many drugs as possible. In order to accomplish that objective, Mylan and the competitors with which it already had very profitable collusive relationships – referred to among the co-conspirators as “High Quality” competitors – decided to raise the prices in the markets for drugs the co-conspirators jointly dominated. Mylan had understandings with its highest quality competitors to lead and follow each other’s price increases, and did so with great frequency and success. This resulted in many billions of dollars of harm to the national economy over a period of several years in what the assistant attorney general of Connecticut has described as “‘likely the largest cartel in the history of the United States.’”<sup>1</sup> This price-fixing conspiracy was not limited to a handful of drugs or a handful of rogue operators – Mylan sought to conspire to fix the price of every generic drug it sold for which colluding to fix the price was feasible, and the collusive price-fixing was an integral part of Mylan’s standard operating procedure. Indeed, the attorneys general of over

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<sup>1</sup> Christopher Rowland, *Investigation of Generic “Cartel” Expands to 300 Drugs*, Wash. Post, Dec. 8, 2018 (quoting Joseph Nielsen).

40 states are now investigating price fixing with respect to no less than 300 generic drugs, involving 16 manufacturers – virtually the entire generic drug industry.<sup>2</sup>

17. The evidence that Mylan engaged in this anticompetitive conduct is overwhelming. On December 14, 2016, the attorneys general of 20 states filed a joint complaint against Mylan that was the product of a years-long investigation. Likewise, on May 10, 2019, the attorneys general of over 40 states filed a new antitrust action against Mylan and other generic drug companies. In these complaints, the states detail the fruits of their investigation and tell the story, with great detail and relying on documentation, of how Mylan agreed with its competitors to allocate the markets for numerous generic drugs. Mylan expressly agreed not to compete with other companies for the business of particular wholesalers, and for years, Mylan acted in accordance with that agreement.

18. The evidence that Mylan colluded to fix the prices of generic drugs is likewise clear. The average prices of these drugs in the United States moved in near-perfect unison during the period of the conspiracy, and the prices of these drugs increased suddenly and simultaneously at each drug company at or near the start of that period. The price increases were exponential – the prices of multiple drugs, including, for example, clomipramine and propranolol, increased suddenly by over 1000%. No other explanation for these sudden, synchronized price increases exists – there were no significant increases in the cost of making the drugs, supply shortages or sudden increases in demand for these drugs during this period. Federal law requires drug manufacturers to report potential drug shortages to the FDA, the reasons therefor, and the expected duration of the shortage. No supply disruptions were reported to the FDA during the Relevant Period that would explain the price increases. There were no similar price increases in other countries selling these generic drugs. Moreover, the market for generic drugs is highly susceptible to collusion for a number of reasons

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<sup>2</sup> *Id.*

detailed below. For example, the markets for the Price-Fixed Drugs (as defined below in §VI.E.) are dominated by only a few companies, and this market concentration makes collusion easy.

19. The extreme price increases caused by this generic drug price-fixing cartel, in which Mylan is an active and important player, have imposed, and continue to impose, a searingly unfair burden on nearly all residents of the United States, including children and the elderly, who, without exaggeration, rely on affordable generic drugs for their quality of life, and in some cases, their survival. Generic drugs are a critical part of the healthcare system in the United States, comprising nearly 8 in 10 prescriptions filled. A member survey by the National Community Pharmacists Association found that the massive increases in the prices of generic drugs “are hurting patients and pharmacies’ ability to operate” and that, in some cases, “patients are declining their medication due to increased co-pays.”<sup>3</sup>

20. In this way, Mylan again misled investors about the competition it faced and about the validity of its sales figures. Mylan repeatedly stated to investors that the market for generic drugs was highly competitive. In fact, the markets for at least some of the generic drugs Mylan sold were collusive and lacked any real competition. Mylan’s statements about the basis for its financial performance were also misleading because they failed to disclose that Mylan competed through anticompetitive means, and so failed to tell the whole truth about the bases for Mylan’s financial success. Mylan’s statements suggested that it did not compete through collusion with competitors on prices, when in fact it did, and while Mylan’s collusion certainly violated U.S. antitrust laws, investors cared about such collusion in any event due to the significant liability to which it exposed Mylan.

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<sup>3</sup> National Community Pharmacists Association, *Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), <http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say>.



21. When these frauds concealed by Mylan became known to the investing public, the price of Mylan stock dropped precipitously. In late August 2016, a news article detailed how Mylan had increased the price of the EpiPen by over 500%, revealing the effects of Mylan's anticompetitive conduct and causing public outcry. U.S. Congresspersons then called on Congress and the FTC to investigate Mylan for anticompetitive conduct relating to the EpiPen. Upon this news and other related revelations, the price of Mylan stock fell \$6.17 per share, or more than 12%, between August 19 and August 24, 2016. When the FTC announced on January 30, 2017 that it was investigating Mylan, Mylan's stock price fell further.

22. As more information about Mylan's frauds was revealed to the public, Mylan's stock price continued to fall. On September 2, 2016, *Inside Health Policy* published an article revealing that CMS had informed Mylan that the Company had incorrectly classified the EpiPen as a generic drug under the MDRP, and that Congress was asking CMS and Mylan for an explanation of the classification of the EpiPen as a generic drug. On October 5, 2016, *Bloomberg* published an article revealing CMS's response to the Congressional inquiry and its confirmation that Mylan had incorrectly classified the EpiPen for years. On this news, Mylan's share price fell \$1.95 per share, or 4.65%, to close at \$39.97 per share on September 2, 2016, and fell \$1.19 per share, or more than 3%, to close at \$36.84 per share on October 6, 2016.

23. On November 3, 2016, *Bloomberg News* reported that U.S. prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion. On December 14, 2016, *Bloomberg* reported that two executives, Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals Inc. in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of commercial operations, were "preparing to plead guilty to price-fixing charges" in a scheme that involved unnamed executives

from Mylan. On January 10, 2017, *The Philadelphia Inquirer* published an article stating that Glazer and Malek had admitted to the charges of conspiring to manipulate the prices of generic drugs. On this news, the price of Mylan shares fell \$2.53 per share, or 6.9%, on November 3, 2016, \$0.61 per share, or 1.6%, on December 14, 2016, and \$2.18 per share, or 5.6%, between January 10 and January 12, 2017.

24. On October 31, 2017, the Attorney General of the State of Connecticut issued a press release on behalf of 46 state attorneys general in which he announced that the group would be filing an amended complaint in their antitrust action against Mylan with a link to access the proposed amended complaint. The amended complaint contained extensive new allegations that Mylan had participated in a wide-ranging price-fixing conspiracy, and for the first time named Rajiv Malik (“Malik”), Mylan’s President and Executive Director, as an individual defendant for his direct participation in the conspiracy. The amended complaint also contained additional details regarding the conspiracy between Mylan and other drug companies to allocate the market and fix the prices of generic drugs.

25. On this news, the price of Mylan shares fell \$2.53 per share, or 6.62%, to close at \$35.71 per share on October 31, 2017.

26. On May 10, 2019, after trading hours, the attorneys general of 44 states filed a lawsuit alleging extensive new allegations, including that Mylan and other generic drug companies had engaged in a massive conspiracy to allocate the market for, and fix the prices of, over 100 generic drugs. The complaint made clear that Mylan and its co-conspirators’ anticompetitive activity was so widespread as to be the standard procedure by which these companies operated in the marketplace: each company was entitled to its “fair share” of the market, and the companies agreed to “play nice in the sandbox.”

27. On this news, the price of Mylan shares fell \$2.09 per share, or 9.43%, to close at \$20.08 per share on May 13, 2019.

28. On May 28, 2019, UBS published a report titled “Mylan Inc., Expanded Alleged price fixing creates another overhang – Reiterate Neutral; PT to \$23.” In this report, UBS provided details regarding the potential exposure the Company faced in the 2017 and 2019 antitrust suits by the state attorneys general. Based on this analysis, UBS lowered its 12-month price target from \$31.00 to \$23.00.

29. On this news, the price of Mylan shares fell \$1.08 per share, or 5.69%, to close at \$17.90 per share on May 28, 2019.

30. In total, upon the disclosure of defendants’ wrongful acts and omissions, the market value of Mylan securities plummeted by \$10.9 billion. As a result of defendants’ wrongful acts and omissions, and the precipitous decline in the market value of Mylan’s securities, Plaintiff suffered significant losses and damages.

## **II. JURISDICTION AND VENUE**

31. The claims asserted herein arise under and pursuant to §10(b) of the Exchange Act (15 U.S.C. §78j(b)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

32. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and §27 of the Exchange Act, 15 U.S.C. §78aa.

33. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Mylan N.V.’s stock trades on the Nasdaq Global Select Market (“NASDAQ-GS”), located within this District.

34. In connection with the acts, conduct, and other wrongs alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including, but not limited to, the U.S. mail, interstate telephone communications, and the facilities of the national securities exchange.

### **III. PARTIES**

35. Plaintiff acquired Mylan securities at artificially inflated prices during the Relevant Period and was damaged upon the revelation of the alleged corrective disclosures.

36. Defendant Mylan N.V. is incorporated in the Netherlands. Mylan N.V.'s principal executive offices are located at Building 4, Trident Place, Hertfordshire AL10 9UL, United Kingdom. Mylan N.V., together with its subsidiaries, develops, licenses, manufactures, markets, and distributes generic and specialty pharmaceuticals worldwide. The Company provides generic pharmaceutical products in tablet, capsule, injectable, transdermal patch, gel, cream, or ointment forms, as well as active pharmaceutical ingredients. Among other products, Mylan markets and sells the EpiPen, a branded device for injecting a measured dose of epinephrine by means of auto-injector technology to treat severe allergic reactions. Defendant Mylan Inc. is an indirect wholly owned subsidiary of Mylan N.V. Prior to February 27, 2015, Mylan Inc. preceded Mylan N.V. as the SEC registrant. In early 2015, Mylan Inc.'s business was reorganized under Mylan N.V. and led by the former officers and directors of Mylan Inc. On February 27, 2015, Mylan N.V. succeeded Mylan Inc. as the SEC registrant. Mylan N.V.'s common stock began trading on the NASDAQ-GS on March 2, 2015 under the ticker symbol "MYL."

37. Defendant Mylan Inc. is incorporated in Pennsylvania. Mylan Inc.'s principal executive offices were located at 405 Lexington Avenue, Floor 52, New York, New York 10174 during the Relevant Period.

**IV. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS OVERCHARGING MEDICAID FOR EPIPENS AND BY FAILING TO DISCLOSE THAT IT WAS BEING INVESTIGATED FOR ITS EPIPEN CLASSIFICATION**

**A. The Importance of the EpiPen to Mylan's Business**

38. Ever since Mylan first acquired the EpiPen in 2007, the EpiPen has been enormously important to Mylan's business. As illustrated in the following table, during the Relevant Period, the EpiPen was responsible for between 28% and 95% of Mylan's operating profits – *i.e.*, profits earned from Mylan's normal, core business operations.

<b>Operating Profit by Year (millions USD)<sup>4</sup></b>					
	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>EpiPen</b>	306	393	525	498	671
<b>Total Mylan</b>	1,109	1,135	1,352	1,460	701
<b>% from EpiPen</b>	27.59%	34.63%	38.83%	34.11%	95.64%

39. The EpiPen's paramount importance to Mylan is also reflected in analyst reports covering the Company, which, throughout the Relevant Period, devoted significant attention to the EpiPen and routinely tied Mylan's overall fortunes to the EpiPen.

40. For example, in a report dated August 24, 2016, RBC Capital Markets analyst Randall Stanicky noted that "the importance of [the EpiPen] to [Mylan's] P&L growth over the last several years has been well understood," and that "EPIPEN has been an important growth driver for

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<sup>4</sup> EpiPen operating profits are taken from a September 2016 SEC filing made by Mylan specifically for the purpose of providing profitability information about the EpiPen after Mylan gave testimony on that topic to Congress. That filing explained that "Mylan does not regularly provide profitability analyses for individual products and does not intend in the future to provide product level profitability [sic] analysis for EpiPen or to update this analysis." The figure for 2016 is an estimated figure. Total Mylan operating profits are taken from Mylan's Form 10-Ks, in which they are reported as "Earnings from operations."

[Mylan] the last several years.”<sup>5</sup> J.P. Morgan analyst Chris Schott similarly noted in an October 4, 2016 report that “EpiPen is Mylan’s largest product at >\$1bn in sales.”<sup>6</sup> In fact, Morningstar’s mere four-sentence profile of the Company highlights the EpiPen by name, noting that after revenue from generics, “[r]emaining sales come from a handful of branded products, primarily the epinephrine injector EpiPen.”<sup>7</sup> The EpiPen is the only drug specifically mentioned by name. Indeed, in an October 18, 2016 report, Morningstar analyst Michael Zbinovec wrote that “Mylan’s specialty drug franchise is essentially comprised entirely of EpiPen.”<sup>8</sup>

41. EpiPen sales were also critically important to Mylan’s quarterly earnings results and Mylan’s ability to meet analyst expectations. For example, in a report dated February 11, 2016, BTIG analyst Timothy Chiang wrote that Mylan was “in need of EpiPen after weak Q4” to make up for a weaker than expected fourth quarter in 2015.<sup>9</sup> A few quarters later, when the Company beat expectations, analysts attributed the success to the EpiPen. For instance, in an August 9, 2016 report, Morgan Stanley analyst David Risinger noted that “EpiPen drove EPS slightly above”

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<sup>5</sup> Randall Stanicky, Matthew Won & Ashley Ryu, *Our thoughts on negative EPIPEN pricing “headline”: Direct read to MYL but also implications for TEVA and IPXL*, RBC Capital Markets (Aug. 24, 2016).

<sup>6</sup> Chris Schott, Dana Flanders & Aditi Singhania, *Mylan NV: Updating Estimates for EpiPen; Remain Cautious In NT But Valuation Offers Compelling LT Entry Point*, J.P. Morgan (Oct. 4, 2016).

<sup>7</sup> Michael Waterhouse & Damien Conover, *Mylan’s EpiPen pricing blowback doesn’t dramatically alter the company’s significant challenges*, Morningstar (Oct. 18, 2016).

<sup>8</sup> Michael Zbinovec, *Mylan is digesting Meda while facing EpiPen headline risk*, Morningstar (Oct. 18, 2016).

<sup>9</sup> Timothy Chiang & Ben Shim, *Mylan N.V.: In Need of EpiPen After Weak Q4; Net Model w/ Meda Suggests Much Needed Accretion is Possible; Buy*, BTIG (Feb. 11, 2016).

expectations.<sup>10</sup> Similarly, in an August 10, 2016 report titled “EpiPen takes the driver’s seat,” Barclays analyst Douglas D. Tsao concurred that “EpiPen was clearly the big driver of 2Q results.”<sup>11</sup>

42. EpiPen sales also drove analysts’ ratings and evaluations of Mylan’s financial prospects. Numerous analysts equated risks to the EpiPen business with risks to their evaluations of Mylan as a whole. For instance, J.P. Morgan analysts included “generic competition for EpiPen” as one of three “[r]isks to the downside” for their overall rating of and price target for Mylan, in reports on March 1, 2016, August 10, 2016, October 4, 2016, and October 10, 2016.<sup>12</sup> Morgan Stanley analysts also repeatedly included “FDA approval of pharmacist-substitutable generic EpiPen” as the first risk listed in a section titled “Risks to Achieving Price Target,” including in a February 12, 2016 report and again in an August 9, 2016 report.<sup>13</sup> BTIG analysts similarly stated that one of the three “key risks” to their evaluation of Mylan was “EpiPen revenues not meeting estimates” in a January 21, 2016 report and again in an August 29, 2016 report.<sup>14</sup>

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<sup>10</sup> David Risinger, et al., *Mylan Inc.: EpiPen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

<sup>11</sup> Douglas D. Tsao & Morgan Williams, *Mylan Inc.: EpiPen takes the driver’s seat*, Barclays (Aug. 10, 2016).

<sup>12</sup> Chris Schott, et al., *MYL/TEVA: Positive EpiPen News Supports EPS Upside for MYL*, J.P. Morgan (March 1, 2016); Chris Schott, et al., *Mylan NV: Solid Qtr Lead by EpiPen; Long-Term Growth Trajectory Remains Intact*, J.P. Morgan (Aug. 10, 2016); Chris Schott, et al., *Mylan NV: Updating Estimates for EpiPen; Remain Cautious in NT But Valuation Offers Compelling LT Entry Point*, J.P. Morgan (Oct. 4, 2016); and Chris Schott, et al., *Mylan NV: EpiPen Rebate Settlement and Updated Guidance A Positive*, J.P. Morgan (Oct. 10, 2016).

<sup>13</sup> David Risinger, et al., *Mylan: EpiPen 4Q sales hurt by inventory workdown, not price adjustments as we hypothesized*, Morgan Stanley (Feb. 12, 2016); and David Risinger, et al., *Mylan Inc.: EpiPen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

<sup>14</sup> Timothy Chiang & Ben Shim, *Mylan N.V.: Upping Estimates to Reflect Higher EpiPen Sales; Buy*, BTIG (Jan. 21, 2016); and Timothy Chiang, *Mylan N.V.: MYL to Launch Authorized Generic Version of EpiPen*, BTIG (Aug. 29, 2016).

43. During the Relevant Period, Mylan's sales of the EpiPen through Medicaid accounted for a very significant amount of Mylan's total sales of the EpiPen. In an October 10, 2016 report, UBS analyst Marc Goodman estimated that "Medicaid spending on EpiPen is ~35% of [Mylan's total] 2015 [EpiPen] sales."<sup>15</sup>

44. As Mylan's sales of the EpiPen constituted a massive part of Mylan's business, and as sales of the EpiPen through Medicaid accounted for a very significant part of Mylan's EpiPen sales, Mylan's classification of the EpiPen for the purposes of the MDRP was highly consequential to the Company.

#### **B. Legal Classification of Drugs for the Purposes of the MDRP**

45. Medicaid is a U.S. government insurance program for persons whose income and resources are insufficient to pay for healthcare. Jointly funded by the state and federal governments, Medicaid is the largest source of funding for medical and health-related services for Americans with low incomes.

46. The MDRP, which was created as part of the Omnibus Budget Reconciliation Act of 1990 (the "1990 Act"), requires a drug manufacturer to enter into, and have in effect, a rebate agreement with CMS in order to receive state Medicaid coverage of the manufacturer's drugs. The rebate agreement imposes reporting and rebating requirements on the drug manufacturers. Manufacturers are required to identify all their covered outpatient drugs to CMS and provide CMS pricing data on those drugs. Manufacturers are then responsible for paying a rebate for their covered drugs that have been purchased and dispensed under state Medicaid plans. These rebates are paid by

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<sup>15</sup> Marc Goodman, et al., *Mylan Inc.: We're Still Constructive on MYL*, UBS (Oct. 10, 2016). This estimate relied on the October 5, 2016 letter to Senator Ron Wyden from CMS Acting Administrator Andrew M. Slavitt, which reported that total Medicaid spending on EpiPen from 2011 to 2015 was \$960 million, with \$253 million spent in 2014 and \$365 million in 2015.



drug manufacturers on a quarterly basis to states and are shared between the states and the federal government to offset the overall cost of prescription drugs under Medicaid.

47. The purpose of the MDRP is to ensure that pharmaceutical companies grant appropriate bulk-discounts to government purchasers of prescription drugs that are commensurate with the massive volume of these purchases. CMS, which is part of the Department of Health and Human Services (“HHS”), administers Medicaid in partnership with state governments.

48. However, in creating the MDRP, lawmakers recognized that generic drugs, which generally face significant competition from competitors, are less “overpriced” than brand-name drugs, which are usually patented and unique. Whereas competition usually will bring down the prices of generic drugs to close to the cost to the manufacturers of producing those drugs, market forces will not similarly bring down the prices of brand-name drugs, which are patented or otherwise face no direct competition. Accordingly, lawmakers required drug manufacturers that participate in the MDRP to provide a greater rebate for patented drugs and drugs that otherwise face no competition than for generic drugs, which the government already buys at close-to-cost prices.

49. Drug manufacturers are responsible for correctly classifying their drugs and paying the correct rebate amounts for their drugs under the MDRP. This classification is not complicated. From the very beginning of the MDRP in 1990 to the present, the enabling statute and regulations governing the MDRP have only ever allowed three possible classifications for a drug like the EpiPen for the purposes of the MDRP: (1) a single source drug (“S” drug); (2) an innovator multiple source drug (“I” drug); and (3) a noninnovator multiple source drug (“N” drug).<sup>16</sup> The rule for classifying drugs under the 1990 Act, which has not changed since its enactment, is simple and unambiguous: drugs that are approved under an original NDA must be classified as either “S” or “I” drugs, while

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<sup>16</sup> 42 U.S.C. §1396r-8(k)(7).

drugs that are not approved under an NDA (such as those approved under an abbreviated new drug application (“ANDA”)) must be classified as “N” drugs.<sup>17</sup> An NDA is the application drug manufacturers use to obtain approval to market a new drug, which is generally subject to a patent, whereas an ANDA is the application generic drug manufacturers use to seek approval to market a generic version of a drug already introduced to the market after gaining approval under an NDA. Therefore, under the 1990 Act, all drugs that are approved under NDAs (which are generally patented brand-name drugs) must be classified as S or I drugs, whereas all drugs that are approved under ANDAs (which are generic drugs) are classified as N drugs. No exceptions to this rule are present in the language or intent of the 1990 Act.

50. As for classifying drugs approved under NDAs as either S or I drugs, a drug approved under an NDA must be classified as an I drug if the FDA has determined that the drug has at least one other “therapeutic equivalent,” *i.e.*, another drug available in the United States that offers the same therapeutic benefits as the drug being classified. However, this distinction is insignificant for the purposes of determining the rebate amount owed under the MDRP – all S or I drugs are subject to the higher rebate calculations than those to which N drugs are subject.

51. While under the 1990 Act a drug marketer need only know whether or not a drug was approved for marketing under an NDA in order to classify that drug correctly for the purposes of rebates under the MDRP, a second unambiguous bright-line rule in the statutory language also makes classification simple: *in no event* can a drug that does not face competition from any

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<sup>17</sup> In the language of the statute, a single source drug or S drug is “a covered outpatient drug . . . which is produced or distributed under a new drug application approved by the Food and Drug Administration.” 42 U.S.C. §1396r-8(k)(7). An innovator multiple source drug or I drug is “a multiple source drug [*i.e.*, a drug that has at least one other ‘therapeutically equivalent’ drug] that is marketed under a new drug application approved by the Food and Drug Administration.” *Id.* A noninnovator multiple source drug or N drug is “a multiple source drug that is not an innovator multiple source drug [*i.e.*, is not a drug that is marketed under an NDA approved by the FDA].” *Id.*

therapeutically equivalent drug be classified as a generic or N drug; that is, if a drug is the only drug on the market that, according to the FDA, offers the same therapeutic benefits, that drug cannot be a generic or N drug. Under 42 C.F.R. §447.502, as is relevant for the purposes of this complaint, for a drug to be classified as an N drug there must be “at least one other drug product which . . . [i]s rated as therapeutically equivalent as reported in the FDA’s ‘Approved Drug Products with Therapeutic Equivalence Evaluations.’” That is, under the 1990 Act, a drug has a therapeutic equivalent if such an equivalent is listed in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the “Orange Book.” The Orange Book is not hard to find – it has been available in the FDA’s public reading room since 1990, and has been available on the FDA’s website, in searchable form, since at least 2007.<sup>18</sup>

52. On October 1, 2007, the first regulations promulgated pursuant to the 1990 Act, 42 C.F.R. §447.500 *et seq.*, became effective (the “2007 Regulations”). These regulations largely adopted the statutory definitions of S, I and N drugs, and for the purposes of this complaint, made only one small change to the classification scheme detailed in the 1990 Act: S or I drugs include, in addition to all drugs approved under an NDA, drugs “approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).”<sup>19</sup> These applications are used only for certain medical products, such as vaccines, antibiotics, certain antibodies, blood and blood by-products, and tissue and cellular products. These applications are not used for drugs for the treatment of anaphylaxis. Accordingly, under the 2007 Regulations, the bright-line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remained unchanged; the 2007 Regulations

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<sup>18</sup> The current version of the Orange Book may be found at <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

<sup>19</sup> 42 C.F.R. §447.502 (2007).

simply expanded the bright-line rule by making clear that in addition to all drugs approved under NDAs, all drugs approved under BLAs, PLAs, ELAs and ADAs must also be classified as S or I drugs.

53. On at least two occasions since 2007, CMS has issued guidance regarding the proper classification of drugs under the MDRP. Given that the classification of drugs for the MDRP is extremely straightforward, in both instances, CMS's guidance constituted exactly one paragraph. On January 5, 2010, CMS informed drug companies in Manufacturer Release No. 80:

In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I) and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).<sup>20</sup>

54. On September 12, 2014, CMS repeated the same guidance quoted above in Manufacturer Release No. 91:

In general, covered outpatient drugs that are approved under a new drug application (NDA) should be reported to CMS as either "S" or "I" drugs, while drugs approved under an abbreviated new drug application (ANDA) should be reported to CMS as "N" drugs.<sup>21</sup>

55. The "in general" language in the above-quoted paragraphs is superfluous. No exception to the bright-line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP exists in the statutory language of the 1990 Act or in the 2007 Regulations.<sup>22</sup>

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<sup>20</sup> Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers*, Release No. 80, at 3 (Jan. 5, 2010).

<sup>21</sup> Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers*, Release No. 91, at 3 (Sept. 12, 2014).

<sup>22</sup> Moreover, industry practice and the practice of the CMS is to classify a drug delivery product filed under an NDA as an S or I drug, even if any patents covering the substance delivered by the product have expired.

56. In February 2016, CMS published a Final Rule modifying slightly the definitions of S, I and N drugs found in the 2007 Regulations (the “Final Rule”).<sup>23</sup> The Final Rule became effective April 1, 2016 (the “2016 Regulations”).<sup>24</sup> Under the 2016 Regulations, the basic bright-line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remains unchanged, but the 2016 Regulations introduced a bright-line exception to the rule: an NDA need not be classified as an S or I drug if, and only if, following the effective date of the 2016 Regulations (April 1, 2016), a drug marketer requests that CMS treat a drug approved under an NDA as if it were approved under an ANDA for the purposes of the MDRP, and CMS then expressly determines that a “narrow exception” applies to that drug and grants the drug manufacturer leave to classify the drug as an N drug.<sup>25</sup> Notably, certain classes of drugs are categorically excluded from this “narrow exception.” In guidance published alongside the Final Rule, CMS stated, “the narrow exception will not be considered applicable to drugs . . . that received patent protection or statutory exclusivity.”<sup>26</sup>

57. In summary, from the beginning of the MDRP in 1990 until April 1, 2016, applicable laws and regulations required all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP. After April 1, 2016, applicable regulations required all drugs approved

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<sup>23</sup> Final Rule, 81 Fed. Reg. 5170 (Feb. 1, 2016).

<sup>24</sup> 42 C.F.R. §447.509 (2016).

<sup>25</sup> In the language of the 2016 Regulations, in the definitions of S and I drugs, “an original NDA means an NDA, other than an [ANDA], approved by the FDA for marketing, unless CMS determines that a narrow exception applies.” 81 Fed. Reg. 5170, 5196 (Feb. 1, 2016).

<sup>26</sup> 81 Fed. Reg. 5170, 5191 (Feb. 1, 2016). As explained *infra*, this “narrow exception” cannot apply to Mylan’s classifications during the Relevant Period because: (1) a request for the exception could only be made after the effective date of the 2016 Regulations; (2) to date Mylan has not requested that this “narrow exception” apply to the EpiPen; and (3) in any event, the exception cannot apply to the EpiPen because the EpiPen has “received patent protection.”

under an NDA to be classified as S or I drugs for the purposes of the MDRP, unless CMS finds that after April 1, 2016 a narrow exception applies, and a narrow exception will never apply to drugs that have received patent protection. Moreover, at no point have applicable laws or regulations permitted a drug that does not face competition from any therapeutically equivalent drug to be classified as a generic or N drug.

58. The difference in rebate amounts owed for generic and non-generic drugs is significant. In general, under current regulations, drug manufacturers must pay CMS a rebate of 23.1% of the average manufacturer price of patented drugs classified as S or I drugs, yet the manufacturer need pay a rebate of only 13% of the average manufacturer price of generic or N drugs.<sup>27</sup> A drug manufacturer reaps a substantial financial benefit if it classifies a drug as a generic or N drug for the purposes of the MDRP. Indeed, as explained below, Mylan was able to overcharge Medicaid by over \$700 million as a result of its misclassification of the EpiPen as a generic drug.

### **C. History of Classifications of the EpiPen for the Purposes of the MDRP**

59. The emergency drug auto-injector pen was first invented in the mid-1970s at Survival Technology in Bethesda, Maryland by Sheldon Kaplan. Initially, his device was called the ComboPen, and was purchased by the military for soldiers to use to auto inject nerve agent antidotes in the event of chemical warfare. Kaplan and others eventually recognized that the same auto-injection technology, covered by U.S. Patent No. 4031893, among others, could be used to deliver epinephrine to treat anaphylaxis, and developed the EpiPen for that purpose. In the late 1980s, Survival Technology submitted the EpiPen to the FDA for approval under an NDA, and on December 22, 1987, the FDA approved the NDA, No. 019-430, and permitted the EpiPen to be marketed in the United States.

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<sup>27</sup> 42 C.F.R. §447.509 (2016).

60. When the EpiPen was first reported to CMS for the purposes of the MDRP, the EpiPen was classified accurately as a non-generic S drug.<sup>28</sup> As explained above, under the 1990 Act, all drugs that are approved under NDAs must be classified as S or I drugs. The EpiPen was approved under an NDA, so Survival Technology had to classify it as an S or I drug. Survival Technology accurately classified the drug as an S drug because the drug had no FDA-approved therapeutic equivalents (nor has it ever had any therapeutic equivalents).

61. In 1996, Survival Technology merged with Brunswick Biomedical to form Meridian Medical Technologies Inc. (“Meridian”), and in 1997, Dey Inc. (“Dey”), a subsidiary of Merck KGaA (“Merck”), acquired the exclusive rights to market and distribute the EpiPen from Meridian.<sup>29</sup>

**D. Mylan Knowingly or Recklessly Misclassified the EpiPen for the Purposes of the MDRP Ever Since It Began Selling the EpiPen to Medicaid**

62. On October 2, 2007, Mylan acquired exclusive rights to market the EpiPen from Dey and Dey’s parent company Merck as part of its acquisition of Merck’s generics business. Meridian retained ownership of the patents relating to the EpiPen. Mylan continued Dey’s sales of the EpiPen to Medicaid. From October 2, 2007 to the present, the responsibility of correctly classifying the EpiPen for the purposes of the MDRP shifted to Mylan.

63. As the following facts make clear, from 2007 to the present, Mylan knowingly or recklessly misclassified the EpiPen as a generic N drug for the purposes of the MDRP.

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<sup>28</sup> Letter from Andrew Slavitt, CMS Acting Administrator, to Ron Wyden, U.S. Senator, at 2 (Oct. 5, 2016).

<sup>29</sup> Meridian was acquired in January 2003 by King Pharmaceuticals, which was then acquired by Pfizer, Inc. (“Pfizer”) in 2010; accordingly, Meridian is now a subsidiary of Pfizer. Pfizer, through Meridian, currently owns the non-expired patents on the EpiPen and currently manufactures the EpiPen for Mylan, while Mylan has exclusive rights to sell and market the EpiPen.

**1. Proper Classification of the EpiPen as a Brand-Name Drug Is Straightforward Under Applicable Laws and Regulations**

64. While Mylan is a massive multinational corporation valued at billions of dollars, which had an army of sophisticated lawyers available to provide advice in 2007 and thereafter on the proper classification of the EpiPen, the proper classification of the EpiPen required no sophisticated legal expertise at all.

65. Mylan's classification of the EpiPen as a generic N drug for the purposes of the MDRP was manifestly contrary to the 1990 Act and to the 2007 Regulations, both of which clearly required that all drugs approved under NDAs must be classified as S or I drugs. The question of whether a drug was approved under an NDA is not a puzzle – if Mylan somehow did not gather from Dey the application type under which the EpiPen was approved, Mylan easily could have looked up the application type through the FDA, including through a simple online search.<sup>30</sup> As the EpiPen was approved under an NDA, the 1990 Act and the 2007 Regulations required Mylan to classify the EpiPen as an S or I drug.

66. While there was no ambiguity in this classification requirement, the 1990 Act and the 2007 Regulations also make clear that in no event may a drug that has no FDA-approved therapeutic equivalent be classified as an N drug. Again, whether a drug has an FDA-approved therapeutic equivalent is not a puzzle – under the 1990 Act, a drug has a therapeutic equivalent if such an equivalent is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." The text of the 2007 Regulations themselves included a government website address drug manufacturers could visit to determine whether a drug had a therapeutic equivalent:

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<sup>30</sup> The application type appears at U.S. Food and Drug Administration, Drugs@FDA: FDA Approved Drugs, <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019430> (last visited Dec. 26, 2019).



For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.fda.gov/cder/orange/default.htm> or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857.

67. The EpiPen has never had an FDA-approved therapeutic equivalent. In fact, in recent years Mylan filed a citizen's petition with the FDA in which it argued that the epinephrine auto-injector from a competitor, Teva Pharmaceutical Industries Ltd. ("Teva"), was not therapeutically equivalent to the EpiPen. Mylan argued that Teva's auto-injector lacked certain patented features of the EpiPen and required the user to remove two caps in order to use the device correctly, whereas the EpiPen required the user to remove only one cap before use. Mylan submitted data from studies that, according to Mylan, indicated that users accustomed to using the EpiPen would not be able to reliably use Teva's auto-injector correctly in an emergency due to these differences and others in the designs of the injectors. Mylan expressly argued that a difference in the design of an injector can create a therapeutic advantage for one product over another, even if the two products are both injectors of the same drug. The FDA ultimately determined that Teva's epinephrine auto-injector was not therapeutically equivalent to the EpiPen.

68. As the EpiPen has never had an FDA-approved therapeutic equivalent, the EpiPen cannot be classified as a generic N drug under the 1990 Act and the 2007 Regulations. For this additional reason, Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations.

**2. Mylan Repeatedly Affirmed in SEC Filings the Simple Rule that Drugs Approved Under an NDA Are Brand-Name Drugs for the Purposes of the MDRP**

69. Mylan knew or recklessly disregarded that its classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations. In Mylan's 10-K filings, Mylan admitted that:

The required rebate [under the MDRP] is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs required manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

In these SEC filings, Mylan made clear it understood the MDRP to require drug companies to rebate products based entirely on whether those products were marketed under NDAs or under ANDAs. As the EpiPen was marketed under an NDA, Mylan's own SEC disclosures imply that Mylan was required to give Medicaid the greater rebate applicable to brand-name drugs (of approximately 23% of the average manufacturer's price) for the EpiPen.

### **3. CMS Expressly Informed Mylan Prior to the Start of the Relevant Period that Mylan's Classification of the EpiPen Was Incorrect**

70. CMS expressly told Mylan that its classification of the EpiPen as a generic N drug was incorrect. On March 12, 2009, following the release of a report prepared by the HHS Inspector General ("HHS IG"), titled "Accuracy of Drug Categorizations for Medicaid Rebates," CMS staff requested the HHS IG to provide it with a list of the eight drugs the HHS IG had determined to be incorrectly classified for the purposes of the MDRP in the course of its preparing the report. In response to this request, on March 16, 2009, the HHS IG provided CMS with the list of misclassified drugs, and that list included the EpiPen. Subsequently, CMS notified Mylan about the misclassification. As CMS Acting Administrator Andrew M. Slavitt stated in a letter to Senator Ron Wyden, "[t]he Center for Medicaid and CHIP Services in CMS has, on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs and has expressly told Mylan that [the EpiPen] is incorrectly classified."<sup>31</sup> As CMS itself was expressly informed by the

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<sup>31</sup> Letter from Andrew Slavitt, CMS Acting Administrator, to Ron Wyden, U.S. Senator, at 2 (Oct. 5, 2016).

HHS IG on March 16, 2009 that the EpiPen was misclassified for the purposes of the MDRP, on information and belief, CMS was not derelict in performing its duties and told Mylan that the EpiPen was misclassified for the purposes of the MDRP shortly after having that misclassification highlighted to it by the HHS IG, and well before the start of the Relevant Period.

**4. Since 2004, Four New Patents Covering the EpiPen Have Been Granted, and Mylan Has Vigorously Participated in the Enforcement of Those Patents**

71. Events in the years following Mylan’s initial classification of the EpiPen as an N drug further demonstrate that its misclassification was knowing or, at a minimum, extremely reckless. Since 2004, Meridian has received four additional patents for features that were subsequently integrated into the EpiPen: U.S. Patent Nos. 7,449,012, 7,794,432, 8,048,035, and 8,870,827 (the “EpiPen Patents”). These four patents have a priority date (*i.e.*, the date used to establish the novelty and/or obviousness of a particular invention relative to prior art) of August 6, 2004, and all will expire in 2025. These patents substantially altered the product Mylan acquired from Dey. As Mylan spokeswoman Lauren Kashtan has stated: ““As anyone who has used the product knows, the epinephrine auto-injector we have in the market today is substantially different than the one we acquired.””<sup>32</sup>

72. The issuance of the EpiPen Patents, and Mylan’s designation of these patents as covering the EpiPen, further show that Mylan was acting disingenuously in classifying the EpiPen in effect as a generic rather than as a brand-name drug for the purposes of the MDRP. Mylan’s disingenuousness is underscored by the fact that Mylan vigorously and repeatedly sought to enforce these patents by participating in multiple lawsuits challenging potential generic competitors to the EpiPen.

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<sup>32</sup> Intelligent Investments, *Mylan: \$5 Billion Potential Liability from EpiPen Underpayment of CMS Rebates*, Seeking Alpha, at 6 (Feb. 6, 2017) (quoting statement made to NBC News).

73. In 2009, Meridian and Mylan filed a patent lawsuit (“2009 Lawsuit”) against Teva, which was preparing to introduce an epinephrine auto-injector that would compete with the EpiPen. The 2009 Lawsuit accused Teva of seeking to “manufacture and sell a generic version of . . . [the] highly successful EpiPen® Auto-Injector prior to the expiration of U.S. Patent Nos. 7,449,012 B2 (the “012 patent”) and 7,794,432 B2 (the “432 patent”), which expire on September 11, 2025.”

74. The 2009 Lawsuit noted that Meridian was “the holder of approved New Drug Application No. 019-430, which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3 mg/0.3 mL and 0.15 mg/0.3 mL (‘EpiPen® Autoinjector’).” It also noted that Meridian had “submitted information concerning the ‘012 patent and ‘432 patent for listing in the FDA’s [Orange Book] on July 17, 2009 and September 15, 2010, respectively.” The 2009 Lawsuit further claimed that Teva’s application to the FDA for its classification of its proposed product “constitute[d] an act of infringement” of the EpiPen Patents at issue.

75. A similar lawsuit was filed in 2010 against Sandoz, Inc. (“Sandoz”) (“2010 Lawsuit”). The 2010 Lawsuit challenged the proposed “manufacture and s[ale] [of] a generic version of Plaintiff Meridian’s highly successful EpiPen® Auto-Injector” and asserted the same patents as the 2009 Lawsuit. Like the 2009 Lawsuit, the 2010 Lawsuit asserted that Sandoz’s application to the FDA for its proposed product “constitute[d] an act of infringement” of the EpiPen Patents at issue.

76. In 2011, yet again, Mylan, in concert with Meridian, asserted the EpiPen Patents, this time in a lawsuit (“2011 Lawsuit”) against Intelliject, Inc. (“Intelliject”). Like Teva and Sandoz before it, Intelliject sought to introduce a competitor to the EpiPen. Like the 2009 and 2010 Lawsuits, Mylan, in concert with Meridian and King Pharmaceuticals, asserted the EpiPen Patents to

prevent Intelliject from proceeding to market its product and argued that Intelliject's application to the FDA "constitute[d] an act of infringement" of the EpiPen Patents at issue.

**5. In 2014, the DOJ Issued a Subpoena to Mylan Regarding Mylan's Misclassification of the EpiPen**

77. In November 2014, Mylan received a subpoena from the DOJ as part of the DOJ's investigation into "whether [the] EpiPen® Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs."<sup>33</sup> Accordingly, by November 2014 at the very latest, the government agency responsible for enforcing compliance with the MDRP, the DOJ, had put Mylan on notice that Mylan's classification of the EpiPen for the purposes of the MDRP was potentially incorrect.

**6. Mylan Marketed the EpiPen as a Brand-Name Drug**

78. Mylan's classification of the EpiPen as a generic drug is also in obvious tension with Mylan's treatment of the EpiPen as a brand-name drug for all purposes other than the classification of the drug under the MDRP. After acquiring the rights to the EpiPen, Mylan embarked on a years-long marketing campaign with the express purpose of promoting the EpiPen as an irreplaceable, unequalled, life-saving brand-name drug. That campaign has resulted in the EpiPen brand being compared to "Kleenex" among doctors, according to a 2015 *Bloomberg* article. Indeed, in August 2015, Heather Bresch ("Bresch"), Mylan's Chief Executive Officer ("CEO"), touted "the brand equity with EpiPen" as a reason not to worry about the prospect of impending generics.

79. Further, Mylan tacitly acknowledged that one of the reasons for the EpiPen's skyrocketing prices is that the EpiPen is a brand-name drug, and not a generic drug. Specifically, in December 2016, in the wake of controversy over EpiPen's rising prices, Mylan introduced an

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<sup>33</sup> Mylan N.V., Quarterly Report (Form 10-Q) at 56 (Nov. 9, 2016).

“authorized generic” to the EpiPen priced at \$300, less than half the EpiPen’s list price. Such a measure would not have been needed were the EpiPen truly a generic drug, as Mylan claimed it to be in classifying the EpiPen as a generic N drug for the purposes of the MDRP.

80. Mylan wanted to have it both ways – it wanted to be able to charge the high prices commensurate with brand-name drugs, while reimbursing the government as little as possible under a classification intended to account for the lower profit margins associated with generic drugs. For years, Mylan succeeded in doing so.

**E. Mylan Knowingly or Recklessly Misled Investors Concerning Its Misclassification of the EpiPen**

81. Throughout the Relevant Period, Mylan misled investors about its misclassification of the EpiPen. In its annual and quarterly filings with the SEC, Mylan repeatedly and intentionally and/or recklessly led investors to believe that the classification of its drugs for the purposes of the MDRP was “complex and often involve[d] subjective decisions” and was subject to “risk of errors and differing interpretations.” Moreover, Mylan repeatedly stated that there could be “ambiguity with regard to how to properly calculate . . . payments” to Medicaid. These statements failed to disclose the true situation Mylan faced with respect to its classification of the EpiPen, namely that Mylan’s classification of the EpiPen was blatantly incorrect under applicable law and regulations. The classification of the EpiPen was not complex and did not involve subjective decisions – as explained above, the classification was simple and straightforward and turned simply on whether the drug had been approved under an NDA (a yes or no matter that can be determined by looking on a government website) and whether the drug had therapeutic equivalents (also a yes or no matter that can be determined by looking on a government website). And the classification was not subject to a “risk of error” – that risk of error had materialized, as defendants knew or were reckless in not knowing that the EpiPen was incorrectly classified. Likewise, the classification was not subject to

“differing interpretations” – looking on the FDA website to check whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise.

82. These and defendants’ numerous other misleading statements regarding Mylan’s misclassification of the EpiPen are detailed in §VII, *infra*.

**F. Mylan Knowingly Misled the Public by Implying It Was Not Being Investigated for Its EpiPen Classification When in Fact It Was**

83. Separately and independently, Mylan misled investors regarding whether a government authority had taken a position contrary to Mylan’s position regarding classification of the EpiPen and whether Mylan was being investigated for its EpiPen classification.

84. Throughout the Relevant Period, in its quarterly and annual filings, Mylan stated that “should there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken.” These statements were misleading from the start of the Relevant Period because, as explained above, prior to the Relevant Period CMS had informed Mylan that its classification of the EpiPen was incorrect. Accordingly, there was not merely a possibility that a government agency might take a position contrary to Mylan’s regarding its classification of the EpiPen – rather, a government agency had already taken a contrary position on that subject and had conveyed its contrary position to Mylan.

85. Moreover, in and after November 2014, Mylan’s statements that a government agency “may take a position contrary to a position we have taken” became doubly misleading because, as of that date, the DOJ had already commenced an investigation relating to Mylan’s misclassification of the EpiPen. That is, by November 2014, the DOJ had indicated to Mylan that it had taken a position contrary to Mylan’s with respect to Mylan’s classification of the EpiPen, namely, that there was a substantial likelihood that Mylan had misclassified the EpiPen.

86. Mylan also misled investors concerning whether it was being investigated for its EpiPen classification. From the beginning of the Relevant Period, and in particular from November 2014 until November 2016, Mylan stated in its annual and quarterly SEC filings that “[a]ny failure to comply with [its payment obligations related to Mylan’s participation in Medicaid] could subject [it] to investigation.” In stating that Mylan was subject to a risk of investigation for a failure to comply with its Medicaid payment obligations, including a failure to comply with its obligation to classify the EpiPen correctly for the purposes of the MDRP, without also disclosing that that risk had already materialized when the DOJ commenced an investigation into Mylan’s classification of the EpiPen, Mylan misled investors into believing that no such investigation was underway when, in fact, it was.

87. These and Mylan’s numerous other misleading statements regarding whether a governmental authority had taken a position contrary to its own regarding its classification of the EpiPen and regarding the existence of an investigation into Mylan’s classification are detailed in §VII, *infra*.

**G. Mylan’s Misclassification of the EpiPen and the Significance of the Misclassification Were Revealed Starting in September 2016**

88. Starting in September 2016, the truth about Mylan’s misclassification of the EpiPen for the purposes of the MDRP, and the significance of that misclassification for Mylan’s finances, was revealed to the market over a series of months. Some of these revelations are as follows.

**1. A Bipartisan Group of U.S. Senators Requested that the DOJ Investigate Mylan’s Classification of the EpiPen**

89. In a September 2016 letter, Senator Richard Blumenthal (D-Conn.), Senator Chuck Grassley (R-Iowa), and Senator Amy Klobuchar (D-Minn.) called on Attorney General Loretta Lynch to investigate Mylan’s classification of the EpiPen for the purposes of the MDRP. The letter noted that the EpiPen had not faced any FDA-approved competitors and that Mylan had actively



prevented other drug marketers from introducing competing products; the letter concluded that the EpiPen was an “innovator drug” subject to the higher rebate under the MDRP. The letter stated that the facts “suggest that Mylan may have knowingly misclassified EpiPens, potentially in violation of the False Claims Act and other statutes.”

## **2. Mylan Agreed to Pay a \$465 Million Settlement to the DOJ over Its Misclassification of the EpiPen**

90. On October 7, 2016, Mylan announced in a press release that it had agreed to the terms of a \$465 million settlement with the DOJ and other government agencies “that w[ould] resolve questions that ha[d] been raised about the classification of [the EpiPen Auto-Injector] for purposes of the Medicaid Drug Rebate Program.” The press release explained that “the question in the underlying matter was whether [the] EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs.” The press release further stated that the settlement terms would resolve claims over “whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula.”

91. According to numerous press reports, the settlement terms also required Mylan to pay a higher rebate rate for the EpiPen to Medicaid starting on April 1, 2017.

92. Following Mylan’s press release, numerous members of Congress criticized the DOJ’s settlement with Mylan for being excessively lenient. For example, on October 21, 2016, Senator Elizabeth Warren called the announced settlement “‘shamefully weak’” and “‘shockingly soft.’” According to Senator Warren, the announced settlement size was too small and may have “‘rewarded’ Mylan by allowing it to keep an additional \$65 million that it had made by ‘defrauding Medicare and Medicaid.’” Senator Warren determined that Mylan underpaid at least \$530 million in Medicaid rebates, and financial analysts have determined that Mylan’s underpayments were even

greater.<sup>34</sup> Senator Richard Blumenthal of Connecticut similarly called on the DOJ to reject the announced settlement.

93. On August 17, 2017, Mylan finalized an agreement with the DOJ to pay \$465 million to settle the government's claims that Mylan misclassified the EpiPen to overcharge Medicaid by up to \$1.27 billion. Mylan announced this agreement in a press release issued the same day.

94. In the press release, Mylan effectively admitted that the EpiPen was misclassified by agreeing to reclassify the EpiPen as a brand-name "innovator" drug. The press release stated that "Mylan will reclassify EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017."

### **3. The SEC Opened an Investigation into Mylan Regarding Its Classification of the EpiPen in October 2016**

95. The same day Mylan announced its settlement with the DOJ, October 7, 2016, Mylan received "a document request from the Division of Enforcement at the SEC seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaints."

96. Mylan did not disclose this SEC document request until a month later, in its Form 10-Q filed with the SEC on November 9, 2016.

## **V. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS ENGAGED IN ANTICOMPETITIVE CONDUCT TO ALLOW IT TO INFLATE THE PRICE OF THE EPIPEN**

97. Beyond Mylan's overcharging Medicaid for over a decade for its purchases of the EpiPen, Mylan engaged in anticompetitive conduct during the Relevant Period in an attempt to hinder competition against the EpiPen. Among other things, Mylan offered unusually large rebates

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<sup>34</sup> According to Evercore ISI senior analyst Umer Raffat, Mylan may have shortchanged Medicaid \$707 million over the past five years.

(30% and higher) to third-party payors in the medical insurance market and expressly conditioned those rebates on the payors' dealing exclusively with Mylan.

98. Mylan misled investors by failing to disclose this anticompetitive conduct and the risk this conduct created that Mylan ultimately would be investigated for such conduct. When this conduct was revealed and when the risk of scrutiny of the Company's practices materialized, the price of Mylan stock dropped precipitously, causing Plaintiff's damages.

**A. The Market for Epinephrine Auto-Injectors**

99. Mylan has monopoly power in the market for epinephrine auto-injectors. Since Mylan acquired the EpiPen, the product has accounted for more than 90% of the U.S. market for these devices. Mylan's monopoly power allows it to raise prices without losing sales. As noted above, Mylan has increased the price for the EpiPen more than 500% since it acquired the rights to the device.

100. The overwhelming majority of patients in the United States who purchase epinephrine auto-injectors do so using their insurance coverage for prescription drugs. Accordingly, from 2013 to 2015, commercial insurance companies and pharmaceutical benefits managers (who manage the pharmacy benefits of group health plan sponsors) (together "commercial third-party payors" or "third-party payors") accounted for 71% of the market for epinephrine auto-injectors in the United States. State-based Medicaid plans accounted for an additional 16% of the market.

101. Given the dominance of commercial third-party payors in the market for epinephrine auto-injectors, a drug company seeking to enter this market must have its drug included on the lists of drugs maintained by commercial insurance companies and pharmaceutical benefits managers for which patients will be reimbursed (their "formularies"). These formularies are usually tiered, such that drugs are placed on different levels according to the amount of the co-payment patients are required to pay. As consumers prefer to pay as little as possible out of pocket for their medications,

consumers are incentivized to select drugs on tiers with lower co-pays. If a drug is wholly excluded from a third-party payor's formulary, the drug is not covered and is often too expensive for patients subject to that formulary to purchase without coverage. Prior to 2013, third-party payors covered all available epinephrine auto-injectors (albeit at different tiers), but never excluded particular epinephrine auto-injectors from coverage entirely.

**B. Mylan Excluded Sanofi from the Market for Epinephrine Auto-Injectors by Offering Anticompetitive Rebates to Third-Party Payors Conditioned on Excluding Sanofi's Auvi-Q Auto-Injector**

102. In January 2013, the drug company Sanofi introduced an epinephrine auto-injector, the Auvi-Q, to compete with the EpiPen. Sanofi sold the Auvi-Q for roughly the same price as the EpiPen. The Auvi-Q was a superior auto-injector to the EpiPen in several ways. The device was smaller than the EpiPen and was easier to carry in pockets or bags because its design was flatter than that of the EpiPen. The Auvi-Q was also easier to operate than the EpiPen – the device issued audible voice instructions to permit first-time users or users panicking from an anaphylactic emergency to operate the device correctly without having to read instructions. The market welcomed this innovative device, and the Auvi-Q sold successfully in the first few months following its release.

103. Mylan responded to this new competitive threat by excluding the Auvi-Q from the market. Shortly after the release of the Auvi-Q, Mylan began offering massive rebates to third-party payors on the express condition that the third-party payors not include the Auvi-Q in their formularies among the epinephrine auto-injectors for which those payors would provide reimbursement. Mylan specifically targeted the Auvi-Q by requiring third-party payors to exclude the Auvi-Q, while allowing certain other epinephrine auto-injectors (deemed not to be a threat to the EpiPen) to remain on some third-party payors' formularies. These rebates amounted to 30% or more of the price that Mylan would otherwise have offered. Mylan did not typically offer rebates for the

EpiPen, and when it did so, those rebates were generally low, usually below 10%. Mylan had no legitimate business reason to offer these unprecedented, deep rebates conditioned expressly on excluding the Auvi-Q from the market; they were offered to block that device from competing.

104. Mylan was able to pay for these massive rebates in at least two ways. *First*, Mylan increased the price of the EpiPen significantly (by more than 500% since 2007). *Second*, Mylan's savings from its misclassification of the EpiPen for the purposes of the MDRP helped the Company subsidize these rebates. Indeed, due to Mylan's price increases, the net after-rebate price of the EpiPen actually rose after it began its exclusionary rebates. Mylan offered no rebates or very low rebates when it sold the EpiPen in 2012 for around \$200, but when Mylan began to offer a 30% rebate on the EpiPen and increased its price to around \$300 by 2014, the net price of EpiPen rose to \$210. For this and other reasons, Mylan's rebates did not have any procompetitive effects.

105. Sanofi was unable to offer massive rebates on the Auvi-Q in line with those offered by Mylan for the EpiPen without offering rebates in excess of its revenues from the Auvi-Q. Given Mylan's massive market share, the cost to third-party payors of foregoing Mylan's rebates would have been very significant. As the Auvi-Q accounted for only around 10% of the market for epinephrine auto-injectors, Sanofi would have had to offer rebates far greater than Mylan's for each Auvi-Q device Sanofi sold to a third-party payor in order to match the total value of Mylan's rebates that the payor would have to forego in order to buy the Auvi-Q. Indeed, Sanofi would have had to offer rebates far in excess of its revenues from the Auvi-Q to match Mylan's rebates, given the EpiPen's market share.

106. Mylan's efforts to exclude the Auvi-Q from the market bore fruit. In 2013, many of the largest third-party payors announced that the Auvi-Q would not be covered in their formularies, and in 2014, more than half of the ten largest commercial third-party payors did not cover the Auvi-

Q in order to obtain Mylan's rebates. Mylan successfully blocked the Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine auto-injectors. In 2014, Mylan's anticompetitive rebates blocked the Auvi-Q from about 45% of the individuals covered by commercial third-party payors. In certain states where third-party payors that did not cover the Auvi-Q due to Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market.

107. The decisions of third-party payors not to cover the Auvi-Q also led doctors to decline to prescribe Sanofi's product, which led to Mylan effectively excluding the Auvi-Q from well over 50% of the national market for epinephrine auto-injectors. Doctors are generally familiar with which drugs are broadly covered by insurance, and when doctors know a particular drug is often not covered, or covered at an unfavorable tier, they will often decline to prescribe that drug to a patient.

108. Other pricing practices exacerbated the effect of Mylan's exclusionary rebates and further allowed Mylan to exclude Sanofi from the market. Around the time of Sanofi's release of the Auvi-Q in 2013, Mylan started offering \$0 co-pay coupons for the EpiPen, which allowed customers to purchase the EpiPen without paying a co-pay to the pharmacy. Sanofi responded by also offering \$0 co-pay coupons. However, due to Mylan's rebates to commercial third-party payors, most such payors excluded the Auvi-Q, and most of the payors that did not exclude it nevertheless offered the Auvi-Q only at a less preferred coverage tier. As a result, the co-pay for the Auvi-Q, when it was covered at all, was typically \$50 to \$75, while the co-pay for the EpiPen was only \$25. Accordingly, to compete with Mylan by offering \$0 co-pay coupons for the Auvi-Q, Sanofi had to absorb two to three times more lost revenue than Mylan had to absorb in offering these co-pay coupons.

109. When Mylan's conditional rebates blocking the Auvi-Q took effect around December 2013, within one month, the Auvi-Q's U.S. commercial third-party payor share of the market for epinephrine auto-injectors dropped by nearly 50%, from about 13% to around 8%. This market share dropped to 7% by May 2014. By April 2014, the Auvi-Q's national market share across all payors had slid from a maximum of 11% in mid-2013 to only 6%, while its market share in 2014 had been projected by Sanofi to exceed 20%. By October 2015, the Auvi-Q's national market share was less than half of what Sanofi had projected.

110. By contrast, in Canada, where Sanofi branded and sold an epinephrine auto-injector called "Allerject" that was otherwise identical to the Auvi-Q, Sanofi's product competed well against the EpiPen. In Canada, Allerject and the EpiPen were treated the same on drug formularies due to government regulations, and the two devices were equally available for physicians to prescribe to consumers. Sales of Allerject in its first year on the market (2013) exceeded projections and accounted for 21% of the Canadian epinephrine auto-injector market. This market share rose to 25% by the end of 2014, and to 32% in 2015.

111. In the United States, a few third-party payors included the Auvi-Q in the same coverage tier as the EpiPen. The Auvi-Q's market share for these payors exceeded expectations and reached as high as 20%-25% by the end of 2013 and exceeded 30% in 2015. This success makes clear that the Auvi-Q could have succeeded and gained market share against the EpiPen had Mylan not excluded it from the market.

112. Ultimately, in October 2015, Sanofi decided not to relaunch the Auvi-Q. Sanofi claims that Mylan's conduct substantially contributed to Sanofi's decision to forego its investment in

the Auvi-Q and give up its rights to the product. In April 2017, Sanofi sued Mylan for antitrust violations.<sup>35</sup>

113. In this way, in offering rebates in exchange for exclusive dealing, and at levels that made it impossible for Sanofi to compete, and through other conduct, Mylan used its monopoly power anticompetitively, in a way that violated §2 of the Sherman Antitrust Act, or at a minimum, put Mylan at severe risk of harmful regulatory scrutiny, including lawsuits, investigations, and other governmental action.

## **VI. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS ENGAGED IN THE MARKET ALLOCATION FOR AND PRICE-FIXING OF GENERIC DRUGS**

114. During the Relevant Period, Mylan participated in a third massive, and separate, series of frauds on investors – Mylan engaged in a wide-ranging scheme to allocate the market and fix the prices for virtually every generic drug that it marketed, including, but not limited to, Doxy DR, fenofibrate, clonidine-TTS Patch, tolterodine extended release, capecitabine, enalapril, valsartan HCTZ, albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine, methotrexate, nadolol, tizanidine, trifluoperazine HCL, budesonide DR, buspirone hydrochloride, cimetidine tablets, diclofenac potassium, diltiazem HCL, estradiol, fluoxetine HCL, flurbiprofen, fluvastatin sodium, haloperidol, ketoconazole, ketoprofen, nitrofurantoin MAC capsules, pentoxifylline, prazosin HCL, prochlorperazine, tamoxifen citrate, and tolmetin sodium, by agreeing with competitors to raise the

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<sup>35</sup> See *Sanofi-Aventis U.S. LLC v. Mylan Inc.*, No. 2:17-cv-02452 (D.N.J. Apr. 24, 2017). The case has been consolidated in multi-district litigation under *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, No. 17-md-2785 (D. Kan.). On December 21, 2017, the District Court in Kansas denied defendants' motion to dismiss antitrust claims brought in that action, including claims under §2 of the Sherman Antitrust Act, based on the conduct alleged in this complaint. See *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 2785, 2017 U.S. Dist. LEXIS 209710, at \*78 (D. Kan. Dec. 21, 2017).



prices substantially and simultaneously. Mylan misled investors about the competition it faced, the validity of its sales, and the risks the Company faced by failing to disclose that it was engaged in this anticompetitive conduct relating to these generic drugs.

**A. Mylan and Its Co-Conspirators Have for Years Followed Anticompetitive Agreements that Each Company Is Entitled to a “Fair Share” of the Market**

115. For many years, the generic pharmaceutical industry has operated pursuant to an understanding among generic drug manufacturers not to compete with each other and to instead settle for what these competitors refer to as “fair share.”

116. The overarching conspiracy among generic drug manufacturers – which ties together all of the agreements on individual drugs identified in this complaint – is an agreed-upon code that each competitor is entitled to its “fair share” of the market, whether that market is for a particular generic drug or a number of generic drugs. The term “fair share” is generally understood as an approximation of how much market share each competitor is entitled to, based on the number of competitors in the market, with a potential adjustment based on the timing of entry. Once a manufacturer has achieved its “fair share,” it is generally understood that the competitor will no longer compete for additional business. The common goal or purpose of this overarching agreement is to keep prices high, avoid price erosion, and serve as the basis for further supracompetitive price increases.

117. This overarching agreement is widespread across the generic drug industry and is broader even than Mylan and the co-conspirators discussed in this complaint. Mylan was among the most central participants in this overarching conspiracy. While this complaint describes this conspiracy with reference at times to the sale of certain specific drugs, these specific drugs are

merely examples of the operation of this overarching conspiracy, which affected all generic drugs Mylan sold.<sup>36</sup>

118. The exact contours of this “fair share” understanding, which has been in place for many years (and pre-dates any of the specific conduct detailed in this complaint), has evolved over time during the numerous in-person meetings, telephonic communications, and other interactions between generic drug manufacturers about specific drugs. These business and social events occur with such great frequency that there is an almost constant ability for Mylan and its co-conspirators to meet in person and discuss their business plans. For example, between February 20, 2013 and December 20, 2013 (a 41-week period), there were at least 44 different tradeshows or customer conferences where Mylan and its co-conspirators had the opportunity to meet in person. These in-person meetings gave Mylan and its co-conspirators the opportunity and cover to have these conversations, and reach these agreements, without fear of detection.

119. The “fair share” understanding among Mylan and its co-conspirators dictates that when two generic drug manufacturers enter the market at the same time, they generally expect that each competitor is entitled to approximately 50% of the market. When a third competitor enters, each competitor expects to obtain a 33% share; when a fourth competitor enters, each expects 25%; and so on, as additional competitors enter the market.

120. When a generic drug manufacturer is the first to enter a particular drug market on an exclusive basis, it is commonly understood that that manufacturer is entitled to a little more than its proportional share of the market. For example, when Dr. Reddy’s Laboratories, Inc. was about to enter the market for a drug in January 2013, the Vice President of Sales and Marketing explained during negotiations with his competitor that “he views it this way. If they [Dr. Reddy’s] are first and

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<sup>36</sup> See Complaint, *State of Connecticut v. Teva Pharmaceuticals USA, Inc.*, No. 3:19-cv-00710-MPS (ECF No. 1) (D. Conn. May 10, 2019).

others come out after, he deserves 60%. If he launches with others on day [one], he considers fair share 2-50%, 3-33%, 4-25%, etc.”

121. Conversely, those generic drug manufacturers that enter later are typically entitled to a little less than their proportional share. One of the many examples of this occurred in March 2014, when Lupin Pharmaceuticals, Inc. entered the market for the generic drug niacin ER after Teva had previously been exclusive. Nisha Patel of Teva and David Berthold of Lupin spoke directly by phone a number of times during this period, including three calls on March 24, 2014. That same day, David Rekenthaler of Teva sent an internal e-mail to Patel. Here, Teva’s expectation to maintain a 60% share in a two-player market, after being the first in that market, was consistent with the overarching conspiracy.

122. In fact, an employee at Taro Pharmaceuticals USA, Inc. went so far as to create a graphic representation of the industry understanding of “fair share,” taking into account both the number of competitors and order of entry to estimate what Taro’s “fair share” should be in any given market.

123. Although these general parameters are well known, there is no precise method for apportioning “fair share,” because market share is ultimately determined by either winning or maintaining the business of various customers, which is inherently variable in a given year. The shared objective, however, is to attain a state of equilibrium, where no competitors are incentivized to compete for additional market share by eroding price.

124. This scheme to minimize competition and allocate “fair share” is typically implemented as follows. First, Mylan and its co-conspirators allocate the market for an individual drug based on the number of competitors and the timing of their entry so that each competitor obtains an acceptable share of the market. Then the competitors agree on ways to avoid competing

on price and, at times, significantly raise prices. This pattern is frequently followed even in the absence of direct communication between the competitors, demonstrating the universal code of conduct agreed to by Mylan and its co-conspirators.

125. This “fair share” understanding has been particularly effective when a new competitor enters the market – a time when, in a free-functioning, competitive market for generic drugs, prices would be expected to go down. In today’s generic drug markets, a new competitor will either approach or be approached by the existing competitors. Existing competitors will agree to “walk away” from a specific customer or customers by either refusing to bid or submitting a cover bid. The new competitor’s transition into the market is seamless; the new entrant is ceded market share and immediately charges a supracompetitive price. The competitors then continue this process of dividing up customers until the market reaches a new artificial equilibrium. This is referred to as a “stable” market.

126. “Fair share” principles also dictate how generic drug manufacturers respond when a competitor experiences supply issues. If the disruption is temporary, the existing competitors will refrain from taking any action that might upset the market balance. By contrast, if the disruption is for a longer term, the competitors will divide up customers until each player achieves a revised “fair share” based on the number of players remaining in the market.

127. These rules about “fair share” apply equally to price increases. As long as everyone is playing fair, and the competitors believe that they have their “fair share,” the larger understanding dictates that they will not seek to compete or take advantage of a competitor’s price increase by bidding a lower price to take that business. Doing so is viewed as “punishing” a competitor for raising prices – which is against the “rules.” Indeed, rather than competing for customers in the face

of a price increase, competitors often use this as an opportunity to follow with comparable price increases of their own.

128. When a generic drug manufacturer participates in this scheme, and prices stay high, this is viewed as “playing nice in the sandbox.” For example, in December 2014, Teva was approached by a large retail customer on behalf of Greenstone LLC. The customer indicated that Greenstone was entering the market for cabergoline and was seeking to target specific customers. The customer specifically requested that Teva give up a large customer to the new entrant and indicated that “Greenstone has promised to play nice in the sandbox.” After discussing the matter internally, a Teva representative responded to the customer, “[t]ell Greenstone we are playing nice in the sandbox and we will let them have [the targeted customer.]” Similarly, when a generic manufacturer is “playing nice in the sandbox,” it is generally referred to as a “responsible” or “rational” competitor.

129. Adherence to the rules regarding “fair share” is critical in order to maintain high prices. Indeed, that is the primary purpose of the agreement. If even one competitor does not participate (and thus behave in accordance with the larger understanding), it can lead to unwanted competition and lower prices. In the relatively few instances where a competitor prioritizes gaining market share over the larger understanding of maintaining “fair share,” that competitor is viewed as “irresponsible” and is spoken to by other competitors.

130. “Fair share,” “playing nice in the sandbox,” and similar terminology have become part of the industry lexicon, and thus part of the larger understanding between Mylan and its co-conspirators. Generic drug manufacturers actively and routinely monitor their fair share and that of their competitors, as well as discuss customer allocation among each other within the context of agreements on specific drugs.

131. The interdependence among generic drug manufacturers transcends product markets, as these companies make decisions not only based on what impact their actions will have in a given product market, but also on how those actions will impact other product markets where the competitors overlap, and any future markets where they might eventually compete. During the Relevant Period, Mylan and other generic drug manufacturers often communicated about, and colluded on, multiple drugs at any given time. Indeed, it was not uncommon for generic drug manufacturers to communicate with each other about products that they did not sell. For example, on January 1, 2013 – the day before a substantial Mylan price increase on a number of items – Kevin Green from Teva spoke five times with James Nesta (“Nesta”), Mylan’s Vice President of Sales and Vice President of National Accounts. The next day, Green spoke with Armando Kellum of Sandoz. Kellum then sent an internal e-mail to the Sandoz team. Despite the fact that Teva did not sell levothyroxine, Green still conveyed to Sandoz that Mylan raised the price on that product.

132. Unlike their branded counterparts, generic drugs are commodities and generic drug manufacturers are constantly making decisions to enter new markets and leave existing markets. Often these decisions are made, at least in part, based on who the competitors are and how strong the relationship is between the two companies.

133. This interdependence between generic drug manufacturers is further demonstrated by the countless examples of companies sharing sensitive information with competitors as a matter of course. Mylan and its co-conspirators regularly forwarded bid packages from customers (Requests for Proposal) to each other. They also shared information among themselves regarding the terms of their contracts with customers, including pricing terms, price protection, and rebates. Mylan and its co-conspirators used this information to negotiate prices on terms that are more favorable to them, often to the ultimate detriment of payors and consumers. For instance, in December 2013, Teva was

negotiating new price increase language in its customers' contracts and wanted some comfort that its competitors had similar language. On December 23, 2013, Rekenthaler of Teva spoke with Nesta of Mylan three times, including a 13-minute call, to confirm Mylan's position.

134. The scope of the anticompetitive activity is breathtaking. Currently the state attorneys general are investigating collusive activity with respect to over 300 generic drugs involving 16 generic drug manufactures – virtually the entire generic drug industry.

**B. Anticompetitive Activity by Generic Drug Manufacturers Led to Widespread Increases in the Cost of Generic Drugs During the Relevant Period**

135. By 2012, unsatisfied with the mere avoidance of price erosion, Mylan and its co-conspirators embarked on one of the most egregious and damaging price-fixing conspiracies in the history of the United States. Mylan and its competitors sought to leverage the collusive nature of the industry to not only maintain their “fair share” of each generic drug market, but also to significantly raise prices on as many drugs as possible. In order to accomplish that objective, Mylan and its competitors, with which it already had very profitable collusive relationships – referred to among the co-conspirators as “High Quality” competitors – decided to raise prices in the markets for drugs the co-conspirators jointly dominated. Mylan had understandings with its highest quality competitors to lead and follow each other's price increases, and did so with great frequency and success, resulting in many billions of dollars of harm to the national economy over a period of several years.

136. The prices for a large number of generic drugs skyrocketed throughout the Relevant Period. Nearly 10% of generic drugs more than doubled in price between July 2013 and July 2014 alone, according to data from CMS. In the same time period, the price of more than 1,200 generic drugs increased by an average of 448%. A study by Fideres Partners LLP, released on December 22, 2016, identified 90 drugs that had price increases of at least 250% between 2013 and 2016 and that were increased by at least two drug companies around the same time, even though there was no

obvious market reason for the increases. A January 2014 survey of 1,000 members of the National Community Pharmacists Association (“NCPA”) found that more than 75% of the pharmacists surveyed reported higher prices on more than 25 generic drugs, with the prices spiking by 600% to 2,000% in some cases.

137. Mylan’s CEO Bresch informed investors about her inclination to raise prices right around the start of Mylan’s recent price fixing. These comments indicated that Bresch was focused on raising the prices of generic drugs, even though the market forces were pushing the prices of generic drugs down.

138. For example, in Mylan’s October 25, 2012 conference call with investors, Bresch stated: “You’ve heard me quarter after quarter coming and saying we weren’t going to chase the bottom, there’s been irrational behavior and that we would continue to hold steady and control what we can control.”

139. Likewise, in Mylan’s May 2, 2013 earnings call, Bresch stated:

I think that there was very whacked-out prices dirt cheap, literally cheaper than dirt, for some of those older products and the bar needs to go up. It needed to go up from a quality perspective and it needs to go up and get rebalanced from a pricing perspective.

\* \* \*

I think that we have certainly seen that and there’s extremes on both ends, but I think overall, the bar is going up and so that stability and that title go with it. I see that staying because I think people realize the detriment it did to this therapeutic category by having the dynamics in place that were.

**C. Pricing Decisions at Mylan Were Reviewed and Approved by Mylan’s Top Executives, Who Were Fully Aware of Mylan’s Market Allocation and Price-Fixing Activity**

140. The following information from a former employee, which was cited in the third amended complaint filed in *In re Mylan N.V. Secs. Litig.*, No. 1:16-cv-07926-JPO (S.D.N.Y.), on



June 17, 2019 (the “Class Complaint”), corroborates defendants’ admissions and other facts alleged herein.

141. Robert Coury (“Coury”), former CEO of Mylan, and Bresch, by virtue of their responsibilities and activities as CEO of the Company, John Sheehan (“Sheehan”) and Kenneth Parks (“Parks”), by virtue of their responsibilities and activities as Chief Financial Officer (“CFO”) of the Company, and Paul Campbell (“Campbell”), by virtue of his responsibilities and activities as the Company’s Chief Accounting Officer, were privy to, and participated in, Mylan’s fraudulent conduct described in this complaint, including the market allocation and price-fixing schemes described in this section. Bresch, Coury, Campbell, Parks, and Sheehan are referred to collectively as “Top Executives.”

142. A confidential witness (“CW”) has confirmed that Coury and Bresch, as successive CEOs, and Sheehan and Parks, as successive CFOs, each knew of and approved all material drug pricing decisions made by the Company. CW started work at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW worked in Mylan’s Morgantown, West Virginia facility, which was at the time the largest pharmaceutical manufacturing plant in the world. CW was part of several groups that met regularly to assess costs. CW was responsible for cost accounting and overseeing plant manufacturing operations. CW also conducted cost analysis on certain products to assess the current market. In CW’s role as Director of Costing, CW worked directly with Sheehan and Mylan President, Tony Mauro. CW also attended company-wide meetings that were led by Bresch and concerned Company initiatives. CW stated that pricing decisions at Mylan occurred frequently and involved all of Mylan’s top executives. “[Price] was always a topic.” CW stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for

Mylan's drugs. According to CW, Bresch and Coury both discussed price adjustments to Mylan's drugs frequently. "Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing." For example, "[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at." CW understood the "anthrax antibiotic" in question to be doxycycline.

**D. Mylan Conspired with Other Drug Companies to Allocate the Market for Generic Drugs to Maintain Prices at Supracompetitive Levels**

143. When entering a generic drug market, Mylan and other generic drug companies routinely sought out their competitors in an effort to reach agreement to allocate market share, maintain high prices, and/or avoid competing on price. These agreements had the effect of artificially maintaining high prices for a large number of generic drugs and creating an appearance of competition when in fact none existed.

**1. Doxy DR**

144. On December 14, 2016, the attorneys general of 20 states filed a joint complaint against Mylan that was the product of a years-long investigation.<sup>37</sup> In the complaint, the States detail the fruits of their investigation and tell the story, with great detail, of how Mylan agreed to allocate the market for Doxy DR with its competitors in order to maintain and increase the price of

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<sup>37</sup> Complaint ¶55, *Connecticut v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056 (D. Conn. Dec. 14, 2016) (ECF No. 1). On March 1, 2017, Connecticut filed an amended complaint that increased the number of states involved in the litigation from 20 to 40 (the "States"). The multistate group of plaintiff states in the amended complaint includes: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington and Wisconsin.

this drug at and to artificially high levels. The allegations in this subsection are based in whole or in part on that complaint.

145. Prior to 2013, Mylan was the only manufacturer of the generic drug Doxy DR. In 2013, Heritage Pharmaceuticals Inc. (“Heritage”) became interested in selling Doxy DR as well.

146. In mid-2013, Heritage executives began to reach out to Mylan executives in an effort to divide the market in order to refrain from competing with each other on prices.

147. In April 2013, Jason T. Malek (“Malek”), Vice President of Commercial Operations at Heritage, and Heritage CEO Jeffrey Glazer (“Glazer”) met with two executive of Heritage’s parent company, Emcure, and discussed their plans to enter the Doxy DR market and to coordinate how Heritage and Mylan could minimize competition with each other. The group decided that Satish Mehta, the CEO of Emcure, would reach out to Malik, the President and Executive Director of Mylan, to facilitate subsequent communications between Glazer and Malek and their Mylan counterparts.

148. On May 3, 2013, Malek requested that another Heritage employee set up a call between Malek and the Vice President of Sales at Mylan, but that Heritage employee replied that the Vice President of Sales at Mylan had little to do with National Accounts and recommended that Malek contact another individual at Mylan. Malek promptly connected with the Mylan employee through the website LinkedIn. Over the next several weeks, Malek and the Mylan employee communicated by phone on multiple occasions.

149. Mylan and Heritage executives quickly became involved in the price-fixing scheme. On May 7, 2013, Heritage’s President and CEO, Glazer, e-mailed Mylan’s President Malik in an effort to discuss dividing the market for Doxy DR. Malik responded with a phone number where he could be reached in England. Malik and Glazer spoke the next day.

150. During this call, Glazer explained to Malik that Heritage had strong business relationships with two of Mylan's Doxy DR customers – a large wholesaler and a large retail pharmacy – and that Heritage intended to pursue Mylan's business at those two accounts. The two accounts represented approximately 30% of the market.

151. Malik agreed to give up the two accounts to Heritage. Malik specifically cited Heritage's prior agreement to allow Mylan to enter the market for another drug without competition as a reason that Mylan would give up market share to Heritage in this instance. Malik told Glazer that he would let others at Mylan know of the plan.

152. During the course of these communications, Glazer and Malik agreed to allocate the market for Doxy DR between Heritage and Mylan, and agreed further that the two companies would refrain from competing against one another for customers in that market. The objective of this agreement was to avoid a price war that would reduce profitability for both companies.

153. In these communications, Mylan agreed to "walk away" from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business from those accounts to increase Heritage's market share.

**a. The Doxy DR Wholesale Account**

154. In June 2013, Malek met a senior executive of the large national wholesaler at a Healthcare Distribution Management Association ("HDMA") conference in Orlando. Among other things, Malek discussed supplying the wholesaler with Doxy DR and, very shortly thereafter, caused Heritage to submit a detailed product proposal, which Malek followed up by reiterating Heritage's keen interest in supplying the wholesaler with Doxy DR.

155. Concurrently with these discussions, Heritage and Mylan executives worked to allocate the Doxy DR market. For example, on June 11, 2013, a Mylan executive had a 10-minute phone conversation with a counterpart at Heritage about the Doxy DR market, and the Heritage

executive left a voicemail with Malek about the conversation immediately thereafter. Shortly after that, Malek had a 7-minute conversation with the Heritage executive.

156. Similarly, on June 18, 2013, a senior manager at the wholesaler informed a Mylan executive by e-mail about an unsolicited bid for Doxy DR by a new entrant and asked Mylan to submit a bid to retain the contract by June 21, 2013, under the industry custom that an incumbent supplier has a right of first refusal by which it can beat a competitor's price to retain the business.

157. However, because Mylan had agreed to give up the wholesaler's account to Heritage, Mylan did not exercise its right of first refusal, and did not submit a bid.

158. On June 27, 2013, having received no bid from Mylan, the wholesaler entered into a distribution agreement with Heritage for Heritage to be the wholesaler's primary supplier of Doxy DR.

159. To date, Heritage has maintained the Doxy DR business with the wholesaler, and Mylan has not sought to compete for that business.

**b. The Doxy DR Pharmacy Account**

160. A similar set of events played out with respect to the large retail pharmacy account. On July 8, 2013, Heritage submitted a proposal letter to the pharmacy to obtain its Doxy DR business, which the pharmacy initially rejected as being priced too high. Heritage e-mailed a revised bid on July 11, 2013 with a lower price.

161. Concurrently, both Heritage and parent Emcure kept Mylan updated on Heritage's efforts. Heritage particularly wanted to ensure Mylan was committed to the agreement and would cede the pharmacy account to Heritage. Thus, on July 18, 2013, Emcure CEO Satish Mehta spoke to Malik to obtain Malik's assurance. The substance of their conversation was conveyed by Emcure personnel to Glazer by e-mail shortly thereafter.

162. Glazer then e-mailed Malik to set up a call. Malik said he would call Glazer that evening, and indeed left him a voicemail when evening arrived. Glazer returned Malik's call 15 minutes later and the two had a 4-minute conversation. During the call, Glazer explained Heritage's strategy regarding the pharmacy account and Doxy DR in general to Malik and the significance of how Mylan would respond to Heritage's bid for the pharmacy's business. After the call ended, Malik immediately spoke to other Mylan employees. Mylan would later react by ceding the business to Heritage.

163. On August 15, 2013, an executive at the pharmacy informed Mylan of an unsolicited bid for the Doxy DR business and gave Mylan a short turnaround time to submit a counterbid. In accordance with Mylan's agreement with Heritage, Mylan submitted a non-competitive counterbid that it knew would fail. Indeed, later that day, the pharmacy told Mylan the counterbid was not competitive enough and gave Mylan a second chance to further reduce its price. Mylan declined to do so and, as a result, in September 2013 the pharmacy awarded its Doxy DR business to Heritage.

164. To date, Heritage has kept the business and Mylan has not tried to win it back.

**c. Further Efforts to Inflate Doxy DR Prices**

165. Even after Heritage obtained the foregoing two accounts, Heritage and Mylan continued to coordinate their efforts to prop up Doxy DR prices. On several occasions, Heritage refrained from competing with Mylan for other customer accounts so as to avoid upsetting the two companies' arrangement. For example, in a November 25, 2013 e-mail between Malek at Heritage and a contact at Mylan, the issue of one of Mylan's large accounts was discussed. Malek e-mailed Glazer the same day, and Glazer's response confirmed that the purpose of Heritage's agreement with Mylan was to maintain high prices in the market for Doxy DR. Glazer questioned whether Heritage should take any action that might disrupt that agreement. At the conclusion of the discussion,

Heritage declined to pursue the large account so as to maintain the Doxy DR market share balance between Heritage and Mylan.

166. In February 2014, Mayne Pharma (USA), Inc. (“Mayne”) also entered the market for Doxy DR. Mayne approached Heritage, even before it began selling the generic drug, in an attempt to obtain some of Heritage’s market share. For example, on January 7, 2014, an employee at Mayne spoke by phone with an employee at Heritage regarding obtaining some of Heritage’s market share.

167. Shortly thereafter, Mayne made an unsolicited bid for the Doxy DR business of a large drug wholesaler. The bid prompted the wholesaler to approach Mylan, its supplier at the time of Doxy DR, to see whether Mylan would match Mayne’s bid. At the same time, the wholesaler reached out to Heritage to see whether Heritage would also submit a bid for the wholesaler’s Doxy DR business.

168. Internally at Heritage, Malek noted that Heritage had sufficient supply of Doxy DR to meet the requirements of the wholesaler and to place a bid for those requirements, but Malek and others at Heritage worried that Mylan would perceive such a bid as an attack on Mylan’s Doxy DR business in violation of the market allocation agreement between Heritage and Mylan – a violation that could result in Mylan retaliating against Heritage. Accordingly, the day after these internal discussions at Heritage took place, Heritage responded to the wholesaler that it declined to place a bid for the wholesaler’s Doxy DR business. The reason Heritage gave to the customer to explain why it could not submit a bid was that Heritage might not have enough supply to fulfill a contract with the wholesaler. Heritage’s explanation, however, was a lie, because three days later Heritage approached a different customer – a pharmacy chain – and asked if Heritage could bid for that company’s Doxy DR business.

169. In late March 2014, Heritage learned that Mayne had made an unsolicited bid for Doxy DR to one of Heritage's large nationwide pharmacy accounts. On March 31, 2014, Malek e-mailed Mayne and, over the following days and weeks, Mayne and Heritage communicated extensively via text message and e-mail regarding Mayne's unsolicited bid. These communications were conveyed to Heritage CEO Glazer in early April 2014. This conflict was resolved when Mayne agreed to walk away from the large account.

170. In November 2014, Mayne made offers to the OneStop Program of McKesson Corporation ("McKesson"), a drug wholesaler, and Econdisc Contracting Solutions ("Econdisc"), a group purchasing organization that includes Express Scripts, Kroger and Supervalu. Malek contacted personnel at Mayne to discuss the situation and raised the idea that Heritage and Mayne could allocate customers by having Mayne withdraw its offer to McKesson. Malek worked out an agreement with Mayne by November 25, 2014, which Glazer subsequently confirmed. Follow-up communications occurred in December 2014 by text messaging and an in-person meeting at a conference of the American Society of Health-System Pharmacists held on December 9, 2014.

171. The agreement resulted in elimination of price competition and higher prices for Doxy DR. When Econdisc put its business out for bid again in January 2015, Heritage deliberately bid a higher price than Mayne, fulfilling its agreement to walk away from the Econdisc business. Likewise, when Heritage was requested to submit a bid by a large nationwide pharmacy chain in September 2015, it declined to do so after learning Mayne was the incumbent supplier.

172. Mylan and Heritage also continued to honor their agreement to allocate market share of Doxy DR and to avoid competing against each other. For example, on August 29, 2014, Malek e-mailed a contact at Mylan and indicated that their agreement was still in effect.



## **2. Fenofibrate**

173. In 2013, Mylan conspired with Teva and Lupin Pharmaceuticals, Inc. (“Lupin”) to allocate the market for the generic drug fenofibrate. Fenofibrate – also known by brand names such as Tricor – is a medication used to treat cholesterol conditions by lowering “bad” cholesterol and fats (such as LDL and triglycerides) and raising “good” cholesterol (HDL) in the blood.

174. As of the end of 2012, Teva and Lupin were the only major suppliers of generic fenofibrate 48 mg and 145 mg tablets, with Teva having approximately 65% market share and Lupin having approximately 35% market share.

175. On February 27, 2013, K.G., a senior marketing executive at Teva, e-mailed multiple Teva colleagues to seek information on Mylan’s potential entry into the market. In order to get this information, Kevin Green, Director of National Accounts at Teva, called Mylan’s Vice President of National Accounts, Nesta.

176. Over the course of that day, Green and Nesta spoke at least four different times. That same day, Green reported back to K.G. and other Teva colleagues what he had learned: Mylan planned to launch fenofibrate 48 mg and 145 mg sometime around November 2013.

177. A few months later, however, Teva learned that Mylan was moving up its launch date for fenofibrate. In advance of this launch, Teva, Lupin, and Mylan conspired to allocate the market for fenofibrate. On May 8, 2013, Green e-mailed his colleagues at Teva. To assist in Teva’s efforts to allocate the fenofibrate market, Green asked a colleague at Teva for information about Teva’s fenofibrate business. This request for information was reiterated – and its purpose made clear – the following day when K.G. sent an internal e-mail stating that Mylan expected to launch fenofibrate 48 mg and 145 mg tablets and that he needed Teva’s fenofibrate sales and profitability information.

178. Up to this point, executives for Teva, Mylan, and Lupin had all been in regular contact by phone. These calls include at least those listed below. On these calls, Teva, Mylan, and

Lupin executives shared information about Mylan's fenofibrate launch and the plan to allocate market share to Mylan.

Date	Call Type	Target Name	Direction	Contact Name	Duration
5/6/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:32
5/6/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:22:02
5/6/2013	Voice	Green, Kevin (Teva)	Outgoing	Berthold, David (Lupin)	0:01:00
5/7/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:10:31
5/7/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:06
5/7/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:18
5/7/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:11:12
5/7/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Berthold, David (Lupin)	0:02:53
5/8/2013	Voice	Nesta, Jim (Mylan)	Incoming	Berthold, David (Lupin)	0:00:05
5/8/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Berthold, David (Lupin)	0:08:55
5/8/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:20
5/8/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:05
5/8/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:05
5/8/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:03:46
5/9/2013	Voice	Green, Kevin (Teva)	Outgoing	Berthold, David (Lupin)	0:01:00
5/9/2013	Voice	Green, Kevin (Teva)	Incoming	Berthold, David (Lupin)	0:12:00
5/9/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:04:05

179. In one striking example of the coordination between the three companies, Nesta called Green at 2:42 p.m. on May 7 and they spoke for more than 11 minutes. Immediately after hanging up the phone – 2:54 p.m. – Nesta called David Berthold at Lupin and spoke for nearly three minutes.

180. On May 10, 2013, K.G. received the Teva sales and profitability information he requested. After having the information for barely half an hour, and before there was even a formal price challenge by Mylan with any of Teva's customers, K.G. decided Teva would concede its fenofibrate sales to Econdisc to Mylan. By conceding Econdisc to Mylan, Teva would walk away from its single biggest customer (in terms of gross profit) for the 48 mg tablets and the third largest out of six customers (in terms of gross profit) for the 145 mg tablets. The logic, of course, was to

allocate a customer of sufficient size to Mylan so that Mylan would be comfortable with its “fair share” and not need to compete on price to acquire market share.

181. Teva executives immediately reached out to executives at Mylan and Lupin through a series of phone calls. These calls include at least those listed below. On these calls, executives of Teva, Mylan, and Lupin confirmed the market allocation scheme.

Date	Call Type	Target Name	Direction	Contact Name	Duration
5/10/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:28
5/10/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:10:46
5/10/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:02:19
5/10/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Patel, Nisha (Teva)	0:05:25
5/10/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:17
5/10/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:07:26
5/10/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:17:28

182. Teva made good on its agreement to concede Econdisc to Mylan. On May 15, 2013, Econdisc informed Teva that a new market entrant had submitted a competitive offer for fenofibrate 48 mg and 145 mg tablets and asked Teva for a counteroffer to retain Econdisc’s business. Less than an hour after receiving the notice of the price challenge, Green recommended conceding Econdisc. K.G. later agreed.

183. Following Teva’s internal confirmation of the market allocation scheme, Teva executives spoke with executives at Mylan and Lupin numerous times. These calls include at least those listed below. On these calls, executives of Teva, Mylan, and Lupin confirmed that Teva was sticking to the market allocation scheme by conceding Econdisc to Mylan.



Date	Call Type	Target Name	Direction	Contact Name	Duration
5/16/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:36
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:02:07
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:00:07
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:03:12
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:00:04
5/16/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:05:29
5/16/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:34
5/17/2013	Voice	Berthold, David (Lupin)	Outgoing	Nesta, Jim (Mylan)	0:02:21
5/17/2013	Voice	Berthold, David (Lupin)	Incoming	Green, Kevin (Teva)	0:10:06
5/17/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:04
5/17/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:11:50
5/17/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:02:23
5/17/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:09
5/17/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:00:21
5/17/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:11:12
5/17/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:04:25
5/17/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:05
5/17/2013	Text	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:00
5/17/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:16:02

### 3. Clonidine-TTS Patch

184. Clonidine-TTS Patch (“Clonidine-TTS”) – also known by the brand name Catapres-TTS – is a medication in the form of a transdermal patch that is used to treat high blood pressure.

185. As of September 2011, Mylan and Teva were at rough parity in the market for generic Clonidine-TTS, with Mylan having approximately 48.4% market share and Teva having approximately 44.4% market share. At the end of 2011 and beginning of 2012, however, Teva began to take more than its “fair share.”

186. In November 2011, Teva took over Mylan’s business for Clonidine-TTS at Walgreens after Walgreens solicited Teva to provide a bid. Then, in late January 2012, Cardinal Health, Inc. (“Cardinal”) solicited a bid from Teva for a one-time buy to cover an alleged short-term supply shortage that Mylan was experiencing. A few days after Teva submitted its offer to Cardinal for the one-time buy, Cardinal asked Teva to become Cardinal’s primary supplier for Clonidine-

TTS. Believing that Cardinal's request was prompted by Mylan having supply issues, Teva accepted and took over the primary position at Cardinal for Clonidine-TTS.

187. On February 10, 2012, the move of Cardinal's business to Teva prompted K.G. of Teva to order his colleagues to get intelligence on the extent of Mylan's alleged supply issues. That same day, David Rekenthaler of Teva called B.P., a senior national accounts executive at Mylan, to obtain the information and they spoke for six minutes. Later that day, Rekenthaler reported back to his Teva colleagues. Rekenthaler was concerned that Mylan might retaliate against Teva for taking more than its "fair share" without consulting with Mylan. With the awards from Walgreens and Cardinal, Teva was projected to have between 65%-70% market share for Clonidine-TTS.

188. To gain back some market share, Mylan challenged Teva's Clonidine-TTS business at McKesson. Teva attempted to de-escalate the situation. Then, in April 2012, Mylan aggressively challenged Teva's Clonidine-TTS business at CVS to gain back market share and further signal its displeasure with Teva for taking the Cardinal business.

189. Teva heard Mylan's retaliatory message loud and clear. On May 4, 2012, just a few days after losing the CVS Clonidine-TTS business to Mylan, Teva was approached by Cardinal about a different drug, doxazosin. At the time, Mylan was the primary supplier for doxazosin at Cardinal. Cardinal representatives told Teva that Mylan was on backorder for one of the four doxazosin dosage strengths until the end of June 2012, but Cardinal wanted to move the entire doxazosin line to Teva. Teva declined to take this business.

190. On the morning of September 28, 2012, Mylan's Nesta and Teva's Green spoke by phone at least twice, once for 4 minutes and once for 14 minutes. On those calls, Nesta informed Green of Mylan's impending temporary exit from the Clonidine-TTS market. As expected, later in the day on September 28, 2012, Teva began getting solicitations from Mylan customers, such as

Wal-Mart and CVS, seeking a bid from Teva for Clonidine-TTS because Mylan had just issued a temporary discontinuation notice.

191. Mylan's exit from the Clonidine-TTS market presented an opportunity to raise prices and collusively reallocate the market at the inflated prices when Mylan fully reentered the market. For example, in April 2012, before Mylan had challenged Teva's Clonidine-TTS business at CVS, Teva's direct invoice price to CVS for the .1 mg, .2 mg, and .3 mg Clonidine-TTS was \$22.13, \$37.81, and \$54.41, respectively. Mylan's retaliation against Teva drove the prices for CVS down to below \$10.49, \$18.17, and \$26.51 for those dosages, respectively. Because of Mylan's exit from the market, however, when Teva took back the CVS business in October 2012, Teva was able to charge CVS a direct invoice price of \$33.28, \$56.08, and \$80.76, respectively.

192. Mylan and Teva maintained regular contact as former Mylan customers came to Teva because of Mylan's supply issues with Clonidine-TTS. For example, Teva submitted bids to CVS and Wal-Mart – which were ultimately accepted by those companies – on October 4, 2012 and October 5, 2012, respectively. In the days leading up to those bids, Teva and Mylan representatives had at least the following phone calls:

Date	Call Type	Target Name	Direction	Contact Name	Duration
10/1/2012	Voice	Rekenthaler, David (Teva)	Outgoing	B.P. (Mylan)	0:01:00
10/1/2012	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:10
10/1/2012	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:04
10/1/2012	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:06
10/1/2012	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:05:00
10/4/2012	Voice	Green, Kevin (Teva)	Incoming	Nesta, Jim (Mylan)	0:11:00

193. Teva and Mylan representatives continued to keep in contact going forward so that if Mylan reentered the Clonidine-TTS market, Mylan could regain market share without eroding price through competitive bidding. For example, on October 10, 2012, Green and Nesta spoke for 10

minutes. That same day, E.G. of Teva sent an e-mail to Teva national account managers and other senior representatives on this topic.

194. In or about February 2013, Mylan relaunched Clonidine-TTS and began seeking market share. In early March 2013, Mylan sought to secure the Clonidine-TTS business at Econdisc. Rather than competitively bid for the business, Teva's internal documents state that it chose to concede Econdisc back to Mylan. By April 2013, Teva had also conceded McKesson to Mylan.

195. In an internal e-mail dated February 28, 2013, Rekenthaler starkly admitted Teva's willingness to help Mylan regain market share without competition. Because Teva had been able to increase the price at CVS following Mylan's exit, Mylan gave a bid to CVS that was higher than Mylan's prior prices. CVS pushed Mylan to lower its bid in light of its prior prices, but, confident that its brinkmanship would work because of Teva's cooperation, Mylan would not do so. Ultimately, CVS declined Mylan's bid because of Mylan's refusal to lower its bid in light of its prior pricing. Nonetheless, because Mylan's bid to CVS was not competitive – but rather an effort to allocate the market without eroding price – Teva was able to maintain artificially higher prices at CVS.

196. To carry out their scheme to allocate the Clonidine-TTS market without eroding price, representatives of Teva and Mylan remained in regular contact. In February and March 2013 alone, Teva and Mylan representatives called each other at least 33 different times and spoke for nearly 2 hours and 45 minutes.

197. By April 2013, having successfully allocated the market, Mylan and Teva were now conspiring to raise prices on Clonidine-TTS. On April 8, 2013, J.L., a marketing manager at Teva, reported internally to his Teva colleagues, including Rekenthaler, that Mylan had agreed to raise prices.

198. Green knew that Mylan would follow a price increase on Clonidine-TTS because, earlier that day, Green had two phone calls with Nesta, with one lasting one minute and the other lasting eight minutes. In a follow-up call the next day between Green and Nesta lasting 11 minutes, Mylan and Teva reconfirmed their agreement that Mylan would follow a Teva price increase on Clonidine-TTS.

#### **4. Tolterodine Extended Release**

199. Tolterodine Extended Release (“Tolterodine ER”) – also known by the brand name Detrol LA – is a medication used for the treatment of an overactive bladder.

200. Pfizer is the branded drug manufacturer for Detrol LA. To resolve patent-infringement claims against Teva by Pfizer related to Detrol LA, Teva and Pfizer entered into a settlement agreement under which Teva would distribute an authorized generic of Tolterodine ER. To resolve similar claims, Mylan entered into its own settlement agreement with Pfizer, which allowed Mylan to launch its generic version Tolterodine ER. On October 31, 2013, Mylan’s ANDA for Tolterodine ER was approved. Under their respective settlement agreements with Pfizer, this triggering event allowed Teva and Mylan to launch their respective generics on January 2, 2014.

201. Teva planned to launch on January 2, 2014. During the first half of December 2013, Teva was under the impression – based on conversations with potential customers – that Mylan was not in a position to launch until 30 to 60 days after Teva launched. Nonetheless, Teva was considering how to allocate the market with Mylan when it did eventually launch. On December 3, 2013, J.K., a marketing executive at Teva, sent an e-mail to Rekenthaler, K.G., and several other Teva colleagues. To prepare offers and figure out the allocation of customers that would bring Teva its desired 50% to 60% market share, Teva executives were instructed to gather usage data from potential customers.



202. Through the first half of December 2013, as Teva was soliciting usage amounts from potential customers, customers were asking Teva to send in pricing offers before the launch. Teva resisted sending out those offers and instead did not plan to do so until the January 2, 2014 launch date. Teva's delay in putting together pricing for potential customers was part of a plan to drive up the amount it could charge for Tolterodine ER. Specifically, Teva expected that on January 7, 2014, Pfizer would raise the price of branded Detrol LA. This would allow Teva to peg its price to the now inflated price of the branded drug and thereby command a higher price for Tolterodine ER on the January 2, 2014 generic launch date.

203. At the end of the day on December 20, 2013, T.C., an employee at Teva, learned from D.H., an employee at Cardinal, that Mylan intended to launch its Tolterodine ER on January 2, 2014. D.H. further provided T.C. with Mylan's pricing for two dosages.

204. T.C. informed her Teva colleagues of Mylan's plans. K.G. of Teva then worked over the weekend to turn this information into initial pricing for all of Teva's potential customers and then shared it internally. In a telling admission that Teva had no intention to bid competitively for all accounts, K.G. noted that the next step was to coordinate bids. The goal in coordinating bids was to ensure that both Mylan and Teva received their previously stated market share goals.

205. On Monday, December 23, 2013, David Rekenthaler, Vice President of U.S. Generics Sales at Teva, Nisha Patel, Director of Strategic Customer Marketing and Director of National Accounts at Teva, K.G., T.C., and several others at Teva had a telephone conference scheduled from 8:00 a.m. to 9:00 a.m. to discuss the Tolterodine ER launch strategy. Just minutes before the meeting was to start, Rekenthaler tried calling Nesta at Mylan. Nesta returned Rekenthaler's call at 8:15 a.m., which was during Teva's scheduled Tolterodine ER phone conference. Rekenthaler nonetheless answered Nesta's call on his cell phone and the pair spoke for 1 minute, 26 seconds.

Immediately after Teva's scheduled Tolterodine ER phone conference, Rekenthaler tried calling Nesta two more times. At 10:22 a.m., Nesta returned Rekenthaler's calls and the pair spoke for an additional 12 minutes, 2 seconds. During these calls, Rekenthaler and Nesta exchanged the details about their offers to various customers, including the specific contractual language used in their offers.

206. For example, at 10:33 a.m., while Rekenthaler was still on the phone with Nesta, K.G. sent an e-mail to Rekenthaler and others asking about the appropriate contractual language to use in offers about the potential for price increases. Minutes after Rekenthaler finished his call with Nesta, he replied with the exact language, in quotes, that Mylan was using. Most importantly though, during these calls between Nesta and Rekenthaler, Teva and Mylan reached an agreement to allocate the Tolterodine ER market on launch day so that Teva and Mylan could reach their target share without eroding pricing.

207. At 12:12 a.m. on December 23, 2013, K.G. circulated a revised version of Teva's pricing plan for the Tolterodine ER launch. This new version incorporated Teva and Mylan's plan to allocate the market, including the submission of cover bids and abstention from bidding. Notably, the revised pricing plan included a chart identifying the major customers (and their associated market share percentage) that Teva would receive to get close to its desired 60% market share while Mylan would get its desired 40% share.

208. Mylan's and Nesta's acts of submitting cover bids to customers – bids that were meant to appear as genuine bids among competitors but were in fact intentionally uncompetitive – were deceptive acts in furtherance of the scheme to allocate the markets for generic drugs and ultimately to defraud investors, and these acts were independent of the Company's misleading statements.

209. In exchange for Mylan either submitting cover bids or abstaining from bidding on these customers, Teva reciprocated by submitting cover bids and/or refusing to submit bids to customers that Mylan targeted. This is demonstrated by the fact that Teva's newly revised pricing plan now included considerably higher direct invoice prices for major customers allocated to Mylan, including Walgreens, Cigna, Humana, Optum RX, Prime Therapeutics, and Kaiser.

210. In addition to submitting inflated bids for Walgreens, Cigna, Humana, Optum RX, Prime Therapeutics, and Kaiser, Teva agreed to refrain from bidding for certain customers, such as Publix, Ahold, Hannaford, and PVA Health.

211. The following day, on December 24, 2013, Rekenthaler and Nesta had two more calls to confirm and refine Teva and Mylan's market allocation agreement. Those calls lasted for nine minutes and eight minutes, respectively.

## **5. Capecitabine**

212. Capecitabine, also known by the brand name Xeloda, is an anti-cancer chemotherapy drug used to treat a variety of cancers, including breast and colon cancer.

213. To resolve patent litigation, the brand manufacturer, Roche Pharmaceuticals, entered into settlement agreements with various generic drug manufacturers – including Teva and Mylan – that would allow those manufacturers to sell generic capecitabine after a certain period of time.

214. As early as January 2014, both Teva and Mylan were making plans for their eventual launch of capecitabine. Part of this planning included the sharing of information so that they could allocate the market between them. For example, in a January 31, 2014 e-mail, J.P., a national accounts executive at Teva, informed K.G., Rekenthaler, and others at Teva that Mylan was courting a specific customer, Armada Health Care. Teva incorporated the data it received from Mylan into its own launch plan for capecitabine.

215. On February 26, 2014, Nesta called Rekenthaler and the two spoke for 16 minutes. Nesta informed Rekenthaler that Mylan would not be able to launch on time with Teva. Rekenthaler immediately reported this news internally at Teva.

216. In early March 2014, Teva launched as the exclusive generic capecitabine manufacturer. Teva remained the exclusive generic capecitabine manufacturer until Mylan entered in August 2014.

217. On August 4, 2014, Nesta and Rekenthaler spoke by phone three times. On these calls, Nesta informed Rekenthaler that Mylan would soon enter the capecitabine market and the pair discussed how to allocate the market.

218. For example, at 12:46 p.m. that day, Nesta called Rekenthaler and they spoke for a little more than five minutes. Immediately after hanging up the phone, Rekenthaler sent an e-mail to Maureen Cavanaugh, Senior Vice President, Commercial Officer of Teva. Cavanaugh responded that she would be in the office the next day and wanted to discuss it with Rekenthaler in person.

219. Less than an hour later, Rekenthaler sent another e-mail, just to Nisha Patel, asking her to run a customer report and indicating that Mylan would seek the business of three particular companies. Mylan did seek the business for each of these three companies and Teva conceded each of them, pursuant to the agreement Rekenthaler had reached with Nesta.

220. On August 7, 2014, McKesson informed Teva that it had received a bid for capecitabine and gave Teva the opportunity to bid to retain the business. Patel then sent an e-mail to K.G., Rekenthaler, and C.B. at Teva. K.G. questioned whether the competitive bid was coming from Mylan and asked Rekenthaler whether he had any additional information. Rekenthaler did not want to put that information in writing, so he and others at Teva planned to discuss the bid.

221. The result was the market allocation scheme previously agreed to by Nesta and Rekenthaler on behalf of Mylan and Teva. The same day that Mylan put a bid in to McKesson – August 7, 2014 – Nesta and Rekenthaler spoke by phone for nearly 13 minutes. On that call, Rekenthaler and Nesta discussed Mylan’s bid to McKesson and reconfirmed their market allocation scheme.

222. This market allocation scheme was highlighted in other e-mails as well. On August 10, 2014, C.B. e-mailed Rekenthaler, Patel, and K.G. about the plan with respect to Econdisc. Rekenthaler knew Mylan was targeting Econdisc, even though Econdisc had not contacted Teva, because he and Nesta had previously discussed it.

223. The next morning, at 8:30 a.m. on August 11, 2014, Rekenthaler alerted others at Teva that Mylan had received formal approval to market capecitabine. Five minutes later, Rekenthaler received a call from Nesta. After exchanging voicemails, the two spoke at 8:52 a.m. The call lasted nearly six minutes. Shortly after hanging up the phone, at approximately 9:02 a.m., Rekenthaler e-mailed K.G., Patel, and others at Teva.

224. In accordance with their market allocation scheme, Mylan targeted and Teva conceded the capecitabine business at ABC, Econdisc, and McKesson/Rite-Aid.

225. Teva conceded other business as well pursuant to the agreement. On August 14, 2014, for example, a smaller customer – Cigna – informed Teva that it had received a bid for capecitabine. On August 18, 2014, Rekenthaler called Nesta to discuss the market allocation scheme and Mylan’s bid to Cigna. The pair talked for 13 minutes. Teva declined to compete with Mylan’s bid in accordance with the market allocation scheme.

## **6. Enalapril**

226. Enalapril maleate (“Enalapril”), also known by the brand name Vasotec, is a drug used in the treatment of high blood pressure and congestive heart failure. In 2009, the generic drug

company Taro Pharmaceuticals USA, Inc. (“Taro”) discontinued its sales of Enalapril under its own label and effectively exited the market. It continued supplying Enalapril thereafter only to certain government purchasers under the “TPLI” label. By mid- 2013, the Enalapril market was shared by three players: Mylan with 60.3%, Wockhardt USA LLC (“Wockhardt”) with 27.5%, and Teva with 10.7%. Those three companies also coordinated a significant anticompetitive price increase for Enalapril in July 2013.

227. Shortly before the Teva and Wockhardt price increases, on or about July 12, 2013, Ara Aprahamian, the Vice President of Sales and Marketing at Taro, was considering whether to renew or adjust Taro’s price on Enalapril for its national contract (for government purchasers), which was slated to expire in September 2013.

228. In the midst of that coordinated price increase, however, Aprahamian was communicating with both Patel of Teva and M.C., a senior sales and marketing executive at Wockhardt, about Enalapril. As a result of those conversations, Taro’s plans changed.

229. On July 17, 2013 – the same day that Teva was taking steps to implement the price increase – Patel called Aprahamian and left a message. He returned the call and the two spoke for almost fourteen minutes. Then, on July 19, 2013 – the day that both Teva’s and Wockhardt’s price increases for Enalapril became effective – Aprahamian called M.C. at Wockhardt on his office phone and left a message. He then immediately called M.C.’s cell phone, which M.C. answered. They spoke for nearly 11 minutes.

230. On the morning of July 19, 2013, Aprahamian sent an internal e-mail to Taro colleagues signaling a change in plans. Aprahamian followed up with another e-mail shortly thereafter.

231. In the coming months, both Teva and Taro engaged in intensive analyses of how the market should look after Taro's re-launch so that each competitor would have its desired or "fair share" of the market.

232. On July 31, 2013, for example, Patel provided her analysis of the drugs Teva should bid on in response to a request for bids from a major customer, which was largely based on whether Teva had reached its "fair share" targets. Patel authorized the submission of a bid for Enalapril. Prior to sending that e-mail, Patel had spoken to Aprahamian on July 30 (11-minute call) and July 31, 2013 (4-minute call). Based on the agreement between the two companies, and in accordance with the industry's "fair share" code of conduct, Taro understood that it would not take significant share from Teva upon its launch because Teva had a relatively low market share compared to others in the market.

233. In early December 2013, Taro was fully ready to re-enter the Enalapril market. On December 3, 2013, Aprahamian consulted twice by phone with Mylan's senior account executive, M.A., during conversations lasting 2 and 11 minutes.

234. On December 4, 2013, one customer that had recently switched from Wockhardt to Teva expressed an interest in moving its primary business to Taro for the 2.5 mg, 5 mg, 10 mg, and 20 mg strengths of Enalapril. At 4:30 p.m. that afternoon, Aprahamian instructed a colleague to prepare a price proposal for that customer for all four products.

235. Before sending the proposal to the customer, however, Aprahamian sought the input of his competitor, Teva. On December 5, 2013, he and Patel spoke by phone for nearly five minutes.

236. Taro's fact sheet for the Enalapril re-launch generated on the day of Aprahamian's call with Teva showed a market share goal of 15% and pricing identical to Teva's and nearly identical to Wockhardt's and Mylan's.

237. Taro began submitting offers on Enalapril the following day, December 6, 2013. But even with the bidding process underway, Aprahamian made certain to communicate with Mylan's M.A. during a brief phone conversation that afternoon. This particular communication was important since Mylan was the market share leader and Taro was targeting more of Mylan's customers than those of other competitors.

238. Over the next ten days, the discussions between Taro and Mylan continued over how to allocate the Enalapril market. Aprahamian and M.A. talked for ten minutes on December 11, and for seven minutes on December 12.

239. Thereafter, and with the likely consent of Mylan, Aprahamian reported on an internal sales and marketing call on December 16, 2013 that Taro's prior target market share goal of 15% for Enalapril had been raised to 20%.

240. Taro continued to gain share from and coordinate with both Mylan and Wockhardt. For example, in late December, Taro submitted a competitive offer to Morris & Dickson, a Wockhardt customer. This caused M.C. of Wockhardt to call Aprahamian on December 31, 2013 to discuss the situation. During the call, M.C. agreed that so long as Wockhardt was able to retain McKesson as a customer, it would concede Morris & Dickson to Taro. In an e-mail on January 2, 2014, S.K. of Wockhardt conveyed the details to his colleagues.

241. By May 2014 the market was stable, and market share for Enalapril was reasonably distributed among the companies. As Teva was considering whether to bid on specific drugs for a request for proposal sent out by a large wholesaler customer, Patel provided words of caution with regard to Enalapril in an e-mail. The same day she sent that e-mail – May 14, 2014 – Patel spoke to Aprahamian for more than four minutes and exchanged eight text messages with him.



242. By June 2014, Taro had obtained 25% market share for Enalapril in a 4-player market. Mylan and Teva each had approximately 28% market share.

## **7. Valsartan HCTZ**

243. In September 2012, the States' CW-4 ("State AG CW-4"), a senior sales executive at Sandoz, was concerned about her job security at Sandoz and sought to network with executives at competing companies in the hope of obtaining new employment. State AG CW-4 contacted Nesta because she was interested in potentially working at Mylan. She obtained Nesta's phone number from a mutual contact and called to introduce herself. During that phone call, Nesta immediately started talking about competitively sensitive information. Although State AG CW-4 was surprised that Nesta was being so blatant, she did not stop him.

244. In the year that followed, between September 2012 and October 2013, State AG CW-4 and Nesta developed an ongoing understanding that they would not poach each other's customers and would follow each other's price increases. Notably, she and Nesta were not friends and communicated almost exclusively by phone.

245. State AG CW-4 and Nesta coordinated to allocate the market for valsartan HCTZ. Valsartan HCTZ, also known by the brand name Diovan, is used to treat high blood pressure.

246. Diovan was a large volume drug that had sales in the United States of approximately \$1.6 billion for the 12 months ending June 30, 2012.

247. Mylan was the first to file an ANDA to market the generic version – valsartan HCTZ – which, if approved, would give Mylan 180 days of generic exclusivity. Sandoz manufactured the authorized generic. This meant that Sandoz and Mylan would be the only two manufacturers of the generic version of the drug for six months.

248. Mylan and Sandoz launched valsartan HCTZ on the same day – September 21, 2012. In the days leading up to the launch, State AG CW-4 and Nesta spoke at least 21 times by phone

during which they discussed, among other things, allocating market share for this product. These calls are detailed in the table below:

Date	Call Type	Target Name	Direction	Contact Name	Duration
9/6/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:20:01
9/6/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:11
9/6/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:00:05
9/6/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:01:18
9/6/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:05:22
9/7/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:00:43
9/7/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:11:35
9/7/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:01:03
9/12/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:22:22
9/12/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:01:35
9/12/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:00:06
9/13/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:11:26
9/13/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:19
9/13/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:57
9/13/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:05:22
9/13/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:03:30
9/14/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:07:36
9/17/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:09
9/17/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:03:32
9/19/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:02:40
9/19/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:51

249. During these phone calls, Sandoz and Mylan – through State AG CW-4 and Nesta – agreed to divvy up the market so that each competitor obtained roughly a 50% market share.

250. Throughout this time, State AG CW-4 also kept her supervisor, Armando Kellum, Vice President, Contracting and Business Analytics at Sandoz, regularly informed of her discussions with Nesta and met with Kellum in person to discuss her customer accounts, including a meeting on September 14, 2012.

**E. Mylan Entered into Price-Fixing Agreements with Competitors to Fix the Price of Generic Drugs**

251. During the Relevant Period, Mylan entered into and maintained price-fixing agreements with the other major participants in the markets for virtually all of the generic drugs that

it marketed, including but not limited to the generic drugs albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine sodium, methotrexate, nadolol, tizanidine, and trifluoperazine HCL (the “Price-Fixed Drugs”).

### **1. Albuterol Sulfate**

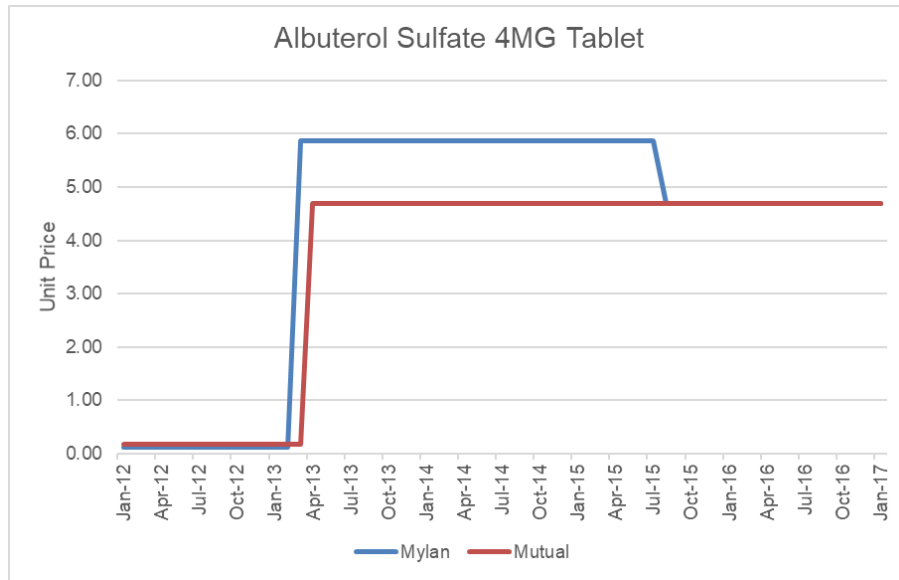
252. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for albuterol sulfate, a bronchodilator used to treat asthma and other respiratory conditions. Senior executives, including CEO Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

253. As shown below in Figure 1, during the Relevant Period, the price at which Mylan sold albuterol sulfate skyrocketed over a matter of days in near perfect synchronization with the price hike of Mutual Pharmaceutical Company, Inc. – the other major marketer of this drug. Figure 1 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of albuterol sulfate.

254. Before 2013, pricing for albuterol sulfate had for years remained stable, as is typical in a mature market. However, as shown in Figure 1, the price of albuterol sulfate charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of albuterol sulfate, including on February 20-22, 2013 in Orlando, Florida, among other meetings.

255. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 1: Albuterol Sulfate**



256. The magnitude by which Mylan and other marketers of albuterol sulfate increased the price of this drug is likewise telling. The average price of common dosages of albuterol sulfate, as measured by National Drug Acquisition Cost (“NADAC”) data, increased by between 2870% and 4266% during the Relevant Period, and the average price of common dosages of the drug increased by between 2653% and 3911% in a matter of days at some point during the Relevant Period.<sup>38</sup>

257. Table 1 below displays percentage increases in NADAC data for common dosages of albuterol sulfate. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set

<sup>38</sup> NADAC is based on CMS’s monthly surveys of retail pharmacies to determine the average acquisition cost for covered outpatient drugs.

for the named drug during the Relevant Period. This table makes clear that the drug cartel's price hikes on albuterol sulfate – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 1: Albuterol Sulfate**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Albuterol Sulfate 2 mg Tab	2013-05-16	<b>3911%</b>	Feb. 2013	Dec. 2015	<b>4266%</b>
Albuterol Sulfate 4 mg Tab	2013-05-23	<b>2653%</b>	Mar. 2013	May 2013	<b>2870%</b>

## **2. Benazepril**

258. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for benazepril, an oral medication used to treat high blood pressure. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

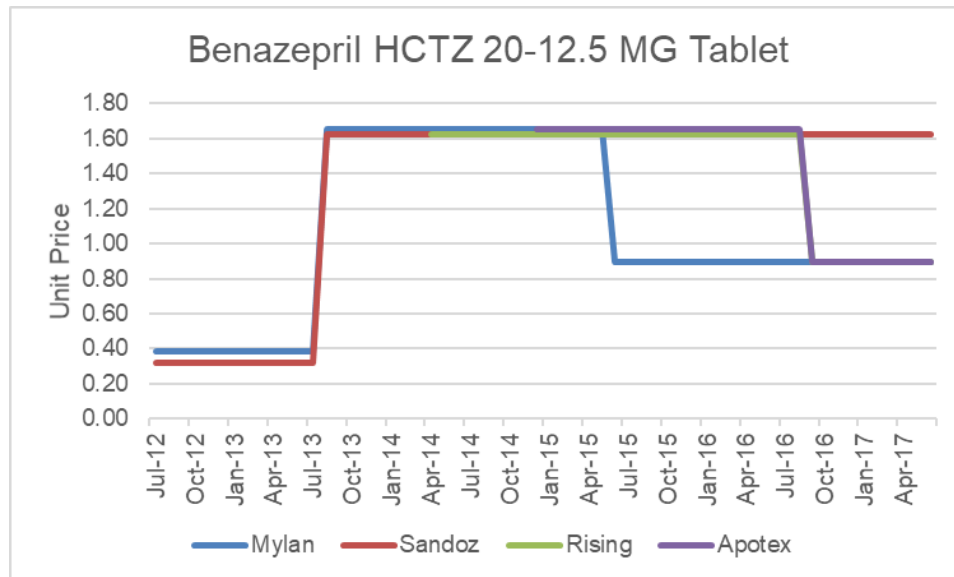
259. As shown below in Figure 2, during the Relevant Period, the price at which Mylan sold benazepril skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure 2 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of benazepril.

260. Before 2013, pricing for benazepril had for years remained stable, as is typical in a mature market. However, as shown in Figure 2, the price of benazepril charged by all major marketers of this drug, including Mylan, increased dramatically in the months following June 2013. This price increase followed meetings of members of generic drug companies during which the

companies, including Mylan, colluded to fix the price of benazepril, including on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

261. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 2: Benazepril**



262. The magnitude by which Mylan and other marketers of benazepril increased the price of this drug is likewise telling. The average price of common dosages of benazepril, as measured by NADAC data, increased by between 331% and 402% during the Relevant Period, and the average price of common dosages of the drug increased by between 263% and 368% in a matter of days at some point during the Relevant Period.

263. Table 2 below displays percentage increases in NADAC data for common dosages of benazepril. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set

for the named drug during the Relevant Period. This table makes clear that the drug cartel's price hikes on benazepril – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 2: Benazepril**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Benazepril-Hydrochlorothiazide 10-12.5 mg Tab	2013-11-21	<b>267%</b>	Apr. 2013	Nov. 2014	<b>377%</b>
Benazepril-Hydrochlorothiazide 20-12.5 mg Tab	2013-10-17	<b>263%</b>	Mar. 2013	Feb. 2014	<b>331%</b>
Benazepril-Hydrochlorothiazide 20-25 mg Tab	2013-11-07	<b>263%</b>	Oct. 2013	July 2015	<b>347%</b>
Benazepril-Hydrochlorothiazide 5-6.25 mg Tab	2014-01-22	<b>368%</b>	Dec. 2013	Oct. 2014	<b>402%</b>

### **3. Clomipramine**

264. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

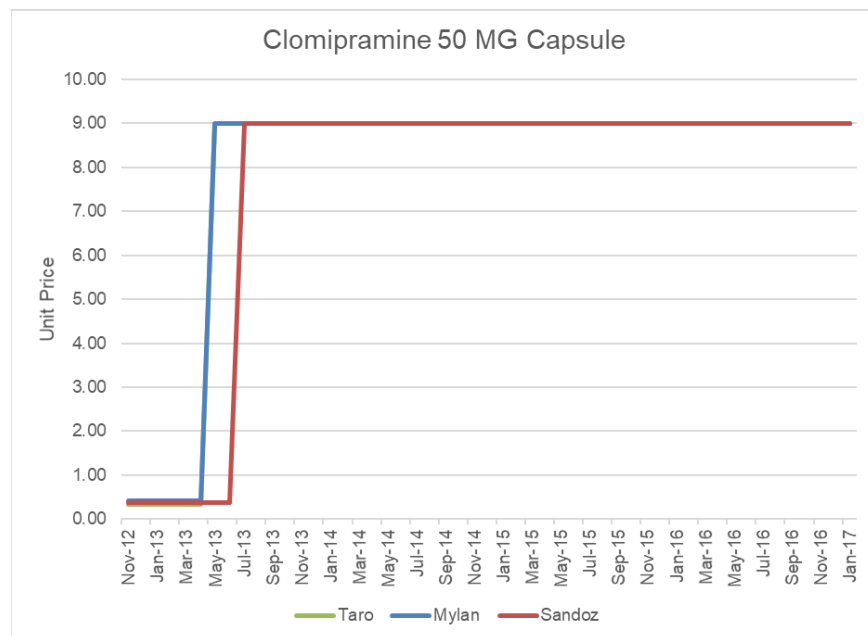
265. As shown below in Figure 3, during the Relevant Period, the price at which Mylan sold clomipramine skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure 3 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of clomipramine.



266. Before 2013, pricing for clomipramine had for years remained stable, as is typical in a mature market. However, as shown in Figure 3, the price of clomipramine charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of clomipramine, including on February 20-22, 2013 in Orlando, Florida, among other meetings.

267. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 3: Clomipramine**



268. The magnitude by which Mylan and other marketers of clomipramine increased the price of this drug is likewise telling. The average price of common dosages of clomipramine, as measured by NADAC data, increased by between 1973% and 3520% during the Relevant Period,



and the average price of common dosages of clomipramine increased by between 1937% and 3482% in a matter of days at some point during the Relevant Period.

269. Table 3 below displays percentage increases in NADAC data for common dosages of clomipramine. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on clomipramine – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 3: Clomipramine**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Clomipramine 25 mg Capsule	2013-06-13	<b>3482%</b>	Apr. 2013	Mar. 2016	<b>3520%</b>
Clomipramine 50 mg Capsule	2013-06-13	<b>2640%</b>	Mar. 2013	June 2013	<b>2701%</b>
Clomipramine 75 mg Capsule	2013-07-11	<b>1937%</b>	Feb. 2013	Nov. 2013	<b>1973%</b>

#### **4. Divalproex**

270. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement Par Pharmaceutical for divalproex, used to treat certain types of seizures and migraines. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

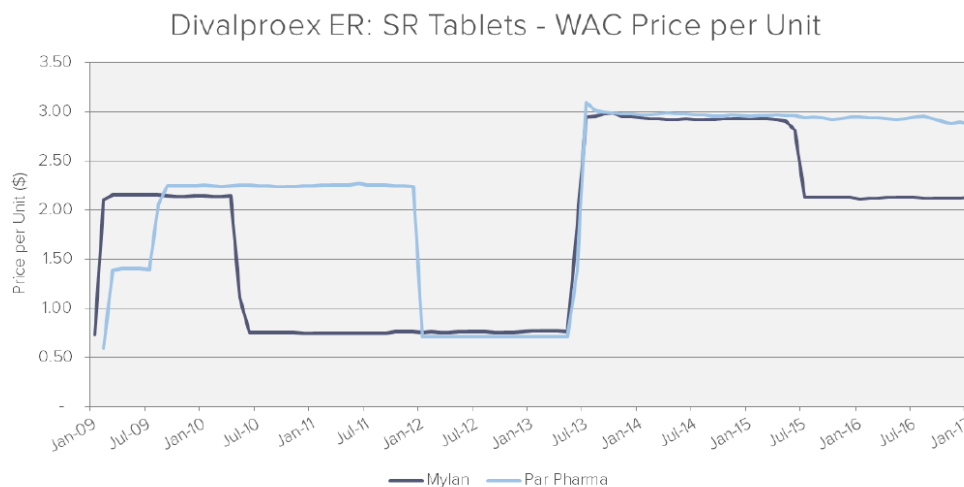
271. As shown below in Figure 4, during the Relevant Period, the price at which Mylan sold divalproex skyrocketed over a matter of days in near perfect synchronization with the price

hikes of Par Pharmaceutical, the other major marketer of this drug. Figure 4 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of divalproex.

272. Before 2013, pricing for divalproex had for years remained stable, as is typical in a mature market. However, as shown in Figure 4, the price of divalproex charged by the major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of divalproex, including on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

273. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 4: Divalproex**



274. The magnitude by which Mylan and Par Pharmaceutical increased the price of this drug is likewise telling. The average price of common dosages of divalproex, as measured by NADAC data, increased by between 685% and 1098% during the Relevant Period, and the average

price of common dosages of divalproex increased by between 561% and 935% in a matter of days at some point during the Relevant Period.

275. Table 4 below displays percentage increases in NADAC data for common dosages of divalproex. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on divalproex – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 4: Divalproex**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Divalproex Sod ER 250 mg Tab	2013-09-19	<b>561%</b>	Mar. 2013	Sep. 2013	<b>685%</b>
Divalproex Sod ER 500 mg Tab	2013-09-19	<b>935%</b>	June 2013	Sep. 2013	<b>1098%</b>

## **5. Propranolol**

276. In or around 2014 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for propranolol, a beta-blocker used to treat and prevent heart attacks and other heart and circulatory conditions. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

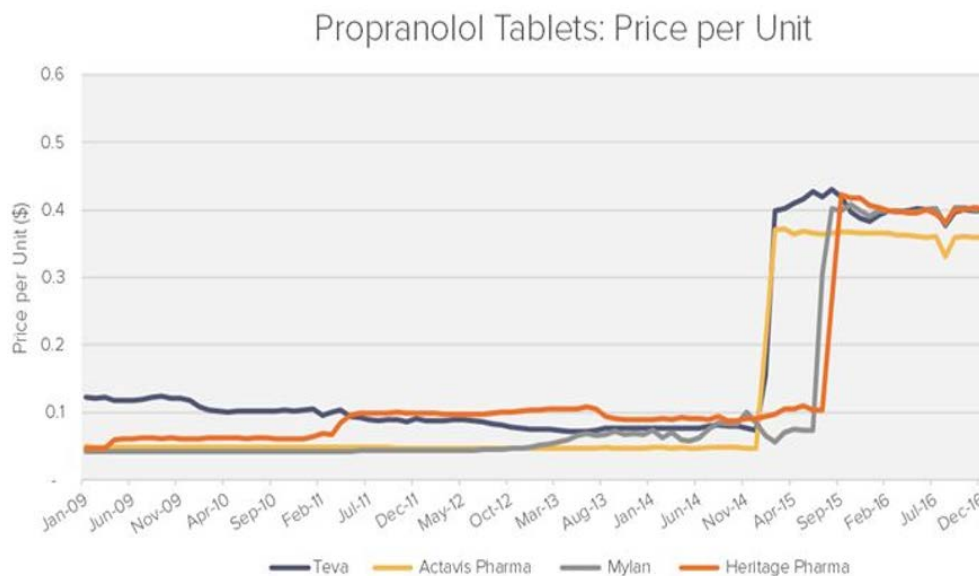
277. As shown below in Figure 5, during the Relevant Period, the price at which Mylan sold propranolol skyrocketed over a matter of days in near perfect synchronization with the price

hikes of the other major marketers of this drug. Figure 5 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of propranolol.

278. Before 2015, pricing for propranolol had for years remained stable, as is typical in a mature market. However, as shown in Figure 5, the price of propranolol charged by all major marketers of this drug, including Mylan, increased dramatically in spring and fall of 2015.

279. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 5: Propranolol**



280. The magnitude by which Mylan and other marketers of propranolol increased the price of this drug is likewise telling. The average price of common dosages of propranolol, as measured by NADAC data, increased by between 111% and 1124% during the Relevant Period, and the average price of common dosages of propranolol increased by between 39% and 356% in a matter of days at some point during the Relevant Period.

281. Table 5 below displays percentage increases in NADAC data for common dosages of propranolol. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on propranolol – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 5: Propranolol**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Propranolol 10 mg Tablet	2015-03-18	<b>210%</b>	Dec. 2014	Sep. 2015	<b>832%</b>
Propranolol 20 mg Tablet	2015-03-18	<b>330%</b>	Oct. 2014	Nov. 2015	<b>1047%</b>
Propranolol 40 mg Tablet	2015-03-18	<b>356%</b>	Oct. 2014	Feb. 2016	<b>1124%</b>
Propranolol 60 mg Tablet	2016-03-23	<b>39%</b>	Nov. 2014	Aug. 2015	<b>111%</b>
Propranolol 80 mg Tablet	2015-03-18	<b>295%</b>	Oct. 2014	Nov. 2015	<b>1113%</b>

282. On January 14, 2014, David Rekenthaler of Teva coordinated a price increase in propranolol with Nesta of Mylan and Marc Falkin, Vice President, Marketing, Pricing and Contracts at Actavis Pharma, Inc. (“Actavis”). The timing and duration of those phone calls are set forth in the table below:

Date	Call Type	Target Name	Direction	Contact Name	Time	Duration
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Falkin, Marc (Actavis)	3:10:00	0:01:00
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	3:12:00	0:01:00
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	5:39:00	0:09:00
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Falkin, Marc (Actavis)	6:29:00	0:03:00

Teva raised its pricing for propranolol on January 28, 2015, and Actavis's price increase on propranolol became effective on February 17, 2015. Rekenthaler then spoke to Nesta twice on February 18, 2015 and again on February 19, 2015. Mylan ultimately followed the Teva and Actavis price increases for propranolol with a price increase of its own on July 10, 2015.

## **6. Amiloride HCL/HCTZ**

283. In or around 2011 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with Teva for amiloride HCL/HCTZ, used to treat high blood pressure (hypertension), heart failure, or extra fluid in the body (edema). Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

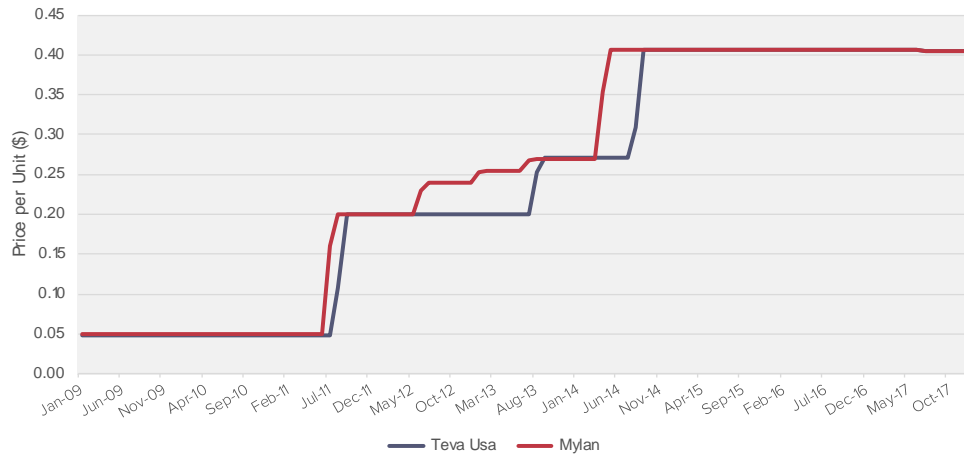
284. As shown below in Figure 6, during the Relevant Period, the price at which Mylan sold amiloride HCL/HCTZ skyrocketed in near perfect synchronization with the price hikes of Teva, the other major marketer of this drug. Figure 6 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of amiloride HCL/HCTZ.

285. Pricing for amiloride HCL/HCTZ had for years remained stable, as is typical in a mature market. However, as shown in Figure 6, the price of amiloride HCL/HCTZ charged by all major marketers of this drug, including Mylan, increased dramatically in 2011, 2013, and 2014-2015.

286. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 6: Amiloride HCL/HCTZ**

Amiloride HCTZ Tablet : Price per Unit



287. The magnitude by which Mylan and Teva increased the price of this drug is likewise telling. The average price of common dosages of amiloride HCL/HCTZ, as measured by NADAC data, increased by between 39% and 90% during the Relevant Period, and the average price of common dosages of amiloride HCL/HCTZ increased by between 20% and 23% in a matter of days at some point during the Relevant Period.

288. Table 6 below displays percentage increases in NADAC data for common dosages of amiloride HCL/HCTZ. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on amiloride HCL/HCTZ – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 6: Amiloride HCL/HCTZ**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Amiloride HCL 5 mg Tablet	2015-01-21	20%	2013-05-23	2015-01-21	39%
Amiloride HCL 5-50 mg Tablet	2014-06-25	23%	2013-09-19	2015-07-22	90%

## **7. Doxazosin Mesylate**

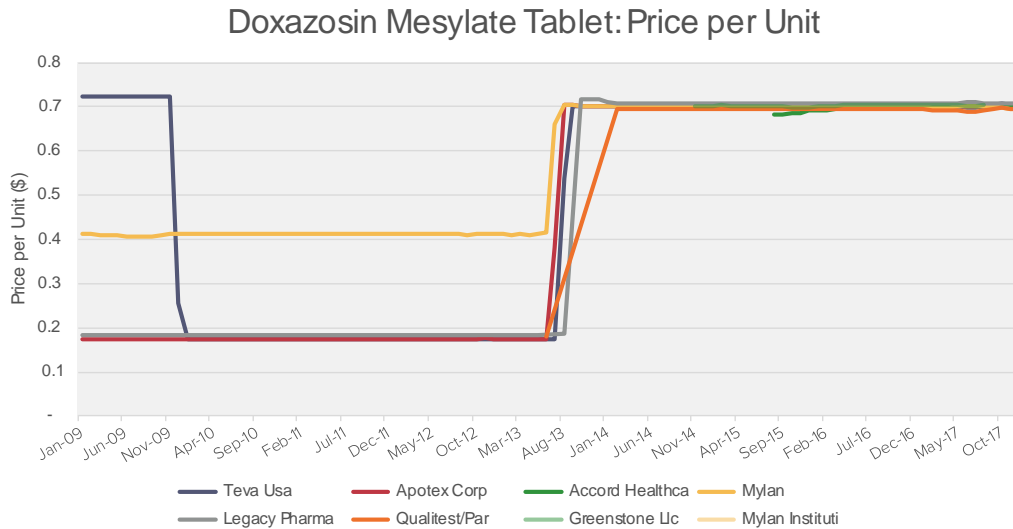
289. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for doxazosin mesylate, an oral medication used to treat symptoms of an enlarged prostate and high blood pressure. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

290. As shown below in Figure 7, during the Relevant Period, the price at which Mylan sold doxazosin mesylate skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure 7 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of doxazosin mesylate.

291. Pricing for doxazosin mesylate had for years remained stable, as is typical in a mature market. However, as shown in Figure 7, the price of doxazosin mesylate charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

292. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanation.



**Figure 7: Doxazosin Mesylate**

293. The magnitude by which Mylan and other marketers of doxazosin mesylate increased the price of this drug is likewise telling. The average price of common dosages of doxazosin mesylate, as measured by NADAC data, increased by between 512% and 1325% during the Relevant Period, and the average price of common dosages of the drug increased by between 230% and 690% in a matter of days at some point during the Relevant Period.

294. Table 7 below displays percentage increases in NADAC data for common dosages of doxazosin mesylate. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on doxazosin mesylate – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 7: Doxazosin Mesylate**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Doxazosin Mesylate 1 mg Tab	2013-10-24	516%	2013-05-23	2014-02-19	1325%
Doxazosin Mesylate 2 mg Tab	2013-08-15	690%	2013-03-21	2013-11-21	1012%
Doxazosin Mesylate 4 mg Tab	2013-10-24	457%	2013-03-21	2013-12-18	804%
Doxazosin Mesylate 8 mg Tab	2013-10-24	230%	2013-03-21	2014-02-19	512%

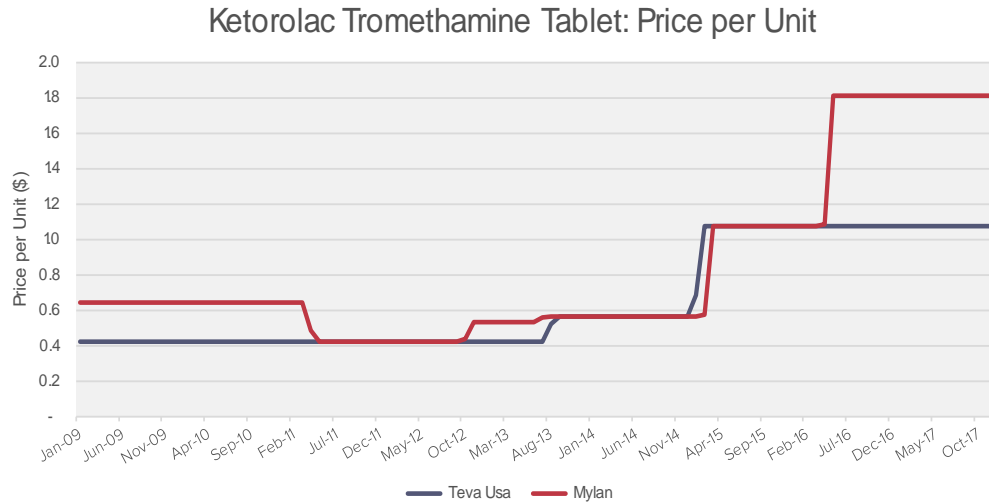
**8. Ketorolac**

295. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with Teva for ketorolac, used to treat pain. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

296. As shown below in Figure 8, during the Relevant Period, the price at which Mylan sold ketorolac skyrocketed over a matter of days in near perfect synchronization with Teva's price hikes. Figure 8 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of ketorolac.

297. Pricing for ketorolac had for years remained stable, as is typical in a mature market. However, as shown in Figure 8, the price of ketorolac charged by the major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

298. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 8: Ketorolac**

299. The magnitude by which Mylan and Teva increased the price of this drug is likewise telling. The average price of a common dosage of ketorolac, as measured by NADAC data, increased by 615% during the Relevant Period, and the average price of a common dosage of ketorolac increased by 192% in a matter of days at some point during the Relevant Period.

300. Table 8 below displays percentage increases in NADAC data for common dosages of ketorolac. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on ketorolac – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 8: Ketorolac**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Ketorolac 10 mg Tablet	2013-10-24	192%	2013-05-23	2017-11-01	615%

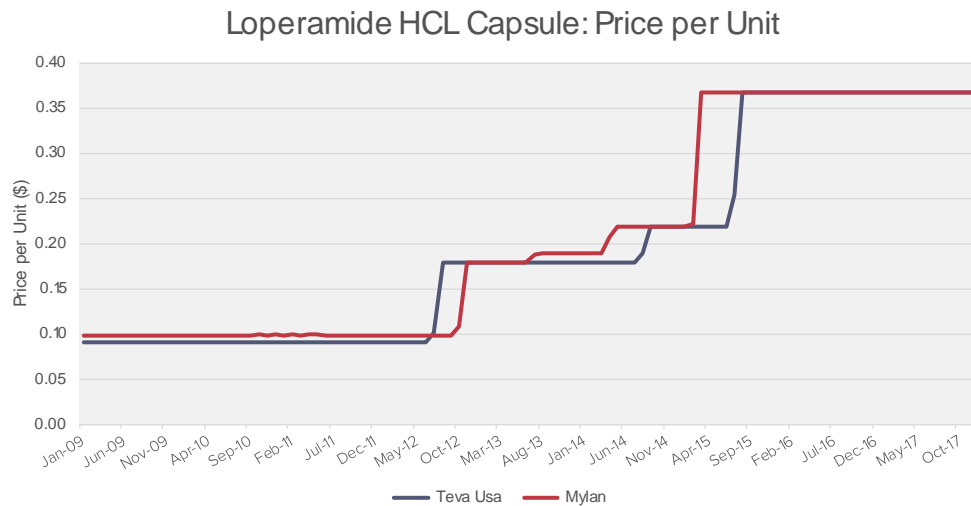
## **9. Loperamide HCL**

301. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with Teva for loperamide HCL, used to decrease the frequency of diarrhea. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

302. As shown below in Figure 9, during the Relevant Period, the price at which Mylan sold loperamide HCL skyrocketed over a matter of days in near perfect synchronization with Teva's price hikes. Figure 9 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of loperamide HCL.

303. Pricing for loperamide HCL had for years remained stable, as is typical in a mature market. However, as shown in Figure 9, the price of loperamide HCL charged by the major marketers of this drug, including Mylan, increased during the Relevant Period.

304. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 9: Loperamide HCL**

305. The magnitude by which Mylan and Teva increased the price of this drug is likewise telling. The average price of a common dosage loperamide HCL, as measured by NADAC data, increased by 159% during the Relevant Period, and the average price of a common dosage of loperamide HCL increased by 36.4% in a matter of days at some point during the Relevant Period.

306. Table 9 below displays percentage increases in NADAC data for common dosages of loperamide HCL. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on loperamide HCL – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 9: Loperamide HCL**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Loperamide 2 mg Capsule	2014-10-15	36.4%	2013-10-24	2016-01-20	159%

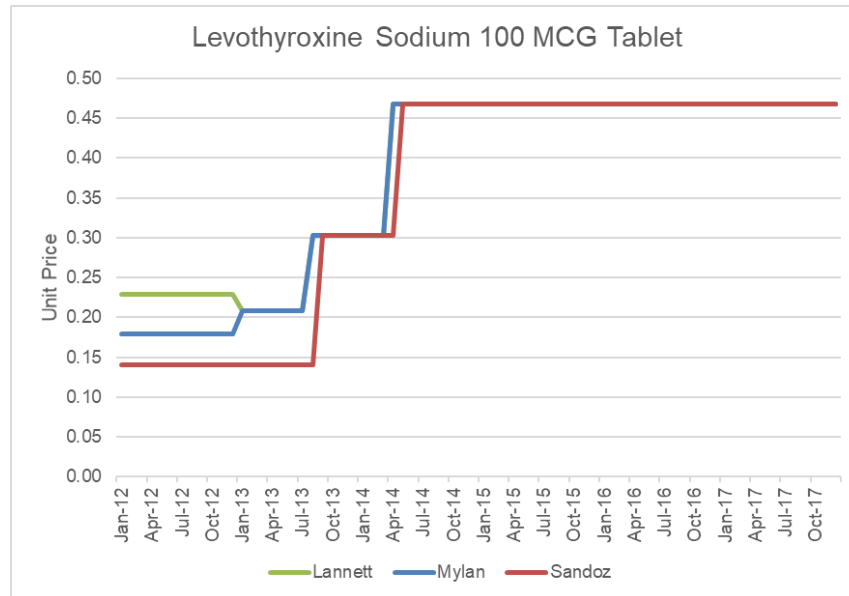
### **10. Levothyroxine Sodium**

307. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for levothyroxine sodium, used to treat thyroid hormone deficiency. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

308. As shown below in Figure 10, during the Relevant Period, the price at which Mylan sold levothyroxine sodium skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure 10 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of levothyroxine sodium.

309. Pricing for levothyroxine sodium had for years remained stable, as is typical in a mature market. However, as shown in Figure 10, the price of levothyroxine sodium charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

310. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 10: Levothyroxine Sodium**

311. The magnitude by which Mylan and other marketers of levothyroxine sodium increased the price of this drug is likewise telling. The average price of common dosages of levothyroxine sodium, as measured by NADAC data, increased by between 239% and 303% during the Relevant Period, and the average price of common dosages of levothyroxine sodium increased by between 53.6% and 93.6% in a matter of days at some point during the Relevant Period.

312. Table 10 below displays percentage increases in NADAC data for common dosages of levothyroxine sodium. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on levothyroxine sodium – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 10: Levothyroxine Sodium**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Levothyroxine 25 mcg Tablet	2013-11-21	72%	2013-02-21	2014-09-17	291%
Levothyroxine 50 mcg Tablet	2013-11-21	93.6%	2013-02-21	2015-02-18	303%
Levothyroxine 75 mcg Tablet	2013-11-21	81.7%	2013-02-21	2014-09-17	294%
Levothyroxine 88 mcg Tablet	2013-11-21	80.9%	2013-02-21	2014-09-17	294%
Levothyroxine 100 mcg Tablet	2013-11-21	83.1%	2013-02-21	2014-09-17	303%
Levothyroxine 112 mcg Tablet	2013-11-21	86.6%	2013-02-21	2014-08-20	298%
Levothyroxine 125 mcg Tablet	2013-11-21	86.4%	2013-02-21	2014-08-20	296%
Levothyroxine 137 mcg Tablet	2013-11-21	62.8%	2013-02-21	2014-09-17	239%
Levothyroxine 150 mcg Tablet	2013-11-21	88.9%	2013-02-21	2014-09-17	286%
Levothyroxine 175 mcg Tablet	2013-11-21	84%	2013-02-21	2014-08-20	294%
Levothyroxine 200 mcg Tablet	2013-11-21	74.2%	2013-02-21	2014-08-20	277%
Levothyroxine 300 mcg Tablet	2013-11-21	53.6%	2013-03-21	2014-08-20	247%

## **11. Methotrexate**

313. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for methotrexate, which is used to treat cancer, autoimmune diseases, ectopic pregnancy, and for medical abortions. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

314. As shown below in Figure 11, during the Relevant Period, the price at which Mylan sold methotrexate skyrocketed over a matter of days in near perfect synchronization with the price

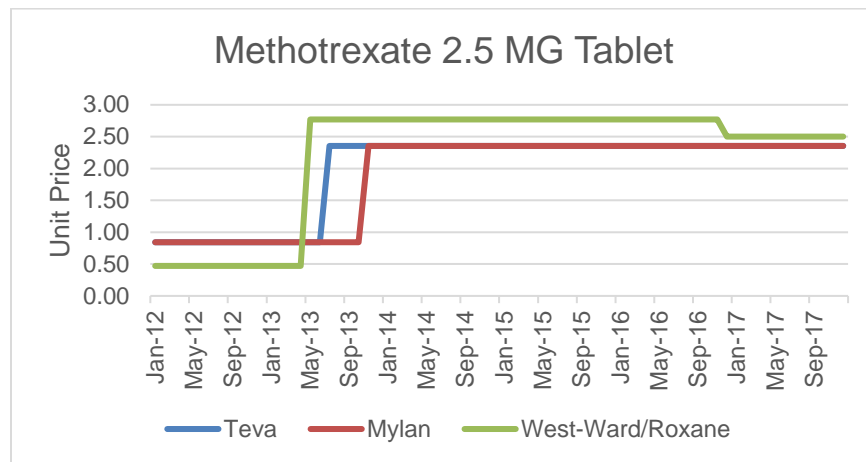


hikes of the other major marketers of this drug. Figure 11 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of methotrexate.

315. Pricing for methotrexate had for years remained stable, as is typical in a mature market. However, as shown in Figure 11, the price of methotrexate charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

316. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 11: Methotrexate**



317. The magnitude by which Mylan and other marketers of methotrexate increased the price of this drug is likewise telling. The average price of a common dosage of methotrexate, as measured by NADAC data, increased by 423% during the Relevant Period, and the average price of a common dosage of methotrexate increased by 308% in a matter of days at some point during the Relevant Period.

318. Table 11 below displays percentage increases in NADAC data for common dosages of methotrexate. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest

% Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on methotrexate – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 11: Methotrexate**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Methotrexate 2.5 mg Tablet	2013-06-06	308%	2013-02-21	2013-07-18	423%

## **12. Nadolol**

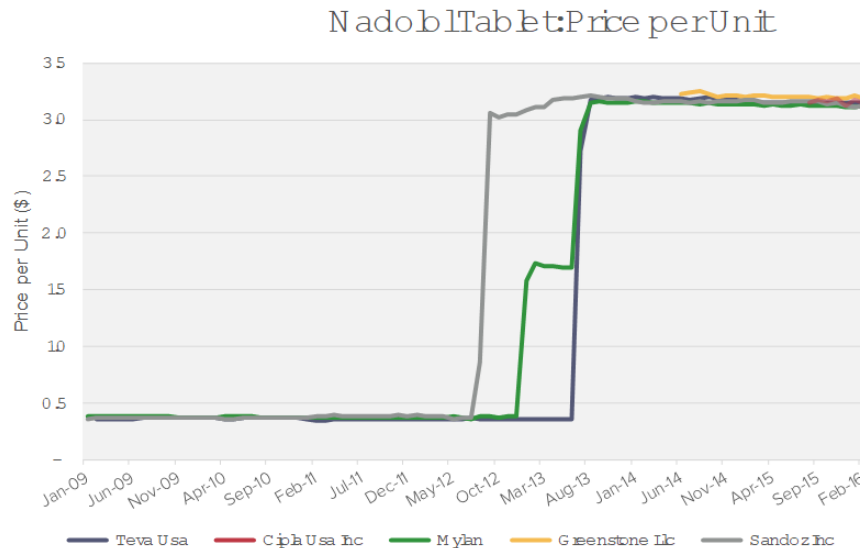
319. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for nadolol, used to treat high blood pressure, heart pain, and atrial fibrillation. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

320. As shown below in Figure 12, during the Relevant Period, the price at which Mylan sold nadolol skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure 12 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of nadolol.

321. Pricing for nadolol had for years remained stable, as is typical in a mature market. However, as shown in Figure 12, the price of nadolol charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

322. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 12: Nadolol**



323. The magnitude by which Mylan and other marketers of nadolol increased the price of this drug is likewise telling. The average price of common dosages of nadolol, as measured by NADAC data, increased by between 77% and 115% in a matter of days at some point during the Relevant Period.

324. Table 12 below displays percentage increases in NADAC data for common dosages of nadolol. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. This table makes clear that the drug cartel’s price hikes on nadolol – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 12: Nadolol**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Nadolol 20 mg Tablet	2013-09-19	77%	N/A	N/A	N/A
Nadolol 40 mg Tablet	2013-09-19	102%	N/A	N/A	N/A
Nadolol 80 mg Tablet	2013-09-19	115%	N/A	N/A	N/A

325. In 2012 and 2013, Mylan's only competitors for nadolol were Teva and Sandoz. All three companies purportedly experienced supply problems of some sort during that time period, but they were in continuous communication to coordinate pricing and market allocation in order to maintain market stability. Nadolol was a high volume drug and one of the most profitable drugs where Mylan, Teva, and Sandoz overlapped, so it was very important that they maintain their coordination.

326. By 2012, an anticompetitive understanding among those companies was firmly in place. Teva raised its price on nadolol on July 31, 2012. In the days leading up to that increase – following a pattern that would become routine and systematic over the following years – Kevin Green, at the time in the sales department at Teva, was in frequent communication with executives at both Sandoz and Mylan. Green spoke to an employee from Sandoz twice on July 29, 2012 and again on July 31, 2012, the day of the price increase. Similarly, Green was communicating with Mylan's Nesta often in the days leading up to the increase, including five calls on the day of the price increase. Sandoz followed with its own increase on August 27, 2012. The increases were staggering – varying from 746% to 2762% depending on the formulation. The day before the Sandoz increase, Armando Kellum, then the Senior Director of Pricing and Contracts at Sandoz, called Teva's Green. They had also spoken once earlier in the month, shortly after the Teva increase. The Sandoz employee also called Green twice on August 21, 2012 – the same day that

Sandoz requested approval from its Pricing Committee to raise the nadolol price. The day after the Sandoz increase, Teva's Green – acting as the conduit of information between Sandoz and Mylan – called Nesta twice, with one call lasting 14 minutes. Mylan, which returned to the market after a brief supply disruption, followed and matched the Teva and Sandoz increases on January 4, 2013. In what had become a routine component of the scheme, the day before the Mylan increase Nesta spoke to Green four times. The next day, Green conveyed the information he had learned from Nesta directly to his counterpart at Sandoz. On January 4, 2013 – the day of the Mylan increase – Green called Kellum twice in the morning, including a six minute call at 9:43 a.m.

327. Green was not speaking with his Sandoz contacts solely about nadolol, the common drug between Teva and Sandoz, but was also conveying information to Sandoz about a Mylan price increase on another drug that Teva did not even sell – levothyroxine. Such conversations further demonstrate the broad, longstanding agreement among each of these competitors to share market intelligence in order to facilitate the scheme.

### **13. Tizanidine**

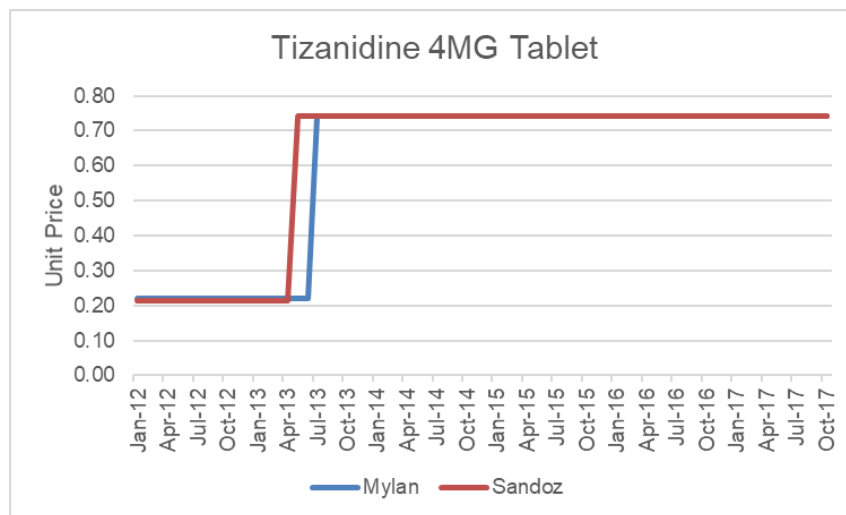
328. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with Sandoz for tizanidine, used to treat muscle spasticity due to spinal cord injury or multiple sclerosis. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

329. As shown below in Figure 13, during the Relevant Period, the price at which Mylan sold tizanidine skyrocketed over a matter of days in near perfect synchronization with Sandoz's price hikes. Figure 13 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of tizanidine.

330. Pricing for tizanidine had for years remained stable, as is typical in a mature market. However, as shown in Figure 13, the price of tizanidine charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

331. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 13: Tizanidine**



332. The magnitude by which Mylan and Sandoz increased the price of this drug is likewise telling. The average price of common dosages of tizanidine, as measured by NADAC data, increased by between 584% and 619% during the Relevant Period, and the average price of common dosages of tizanidine increased by between 129% and 530% in a matter of days at some point during the Relevant Period.

333. Table 13 below displays percentage increases in NADAC data for common dosages of tizanidine. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set

for the named drug during the Relevant Period. This table makes clear that the drug cartel's price hikes on tizanidine – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.

**Table 13: Tizanidine**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Tizanidine HCL 2 mg Tablet	2013-08-22	129%	2013-03-21	2015-02-18	584%
Tizanidine HCL 4 mg Tablet	2013-07-11	530%	2013-05-23	2013-09-19	619%

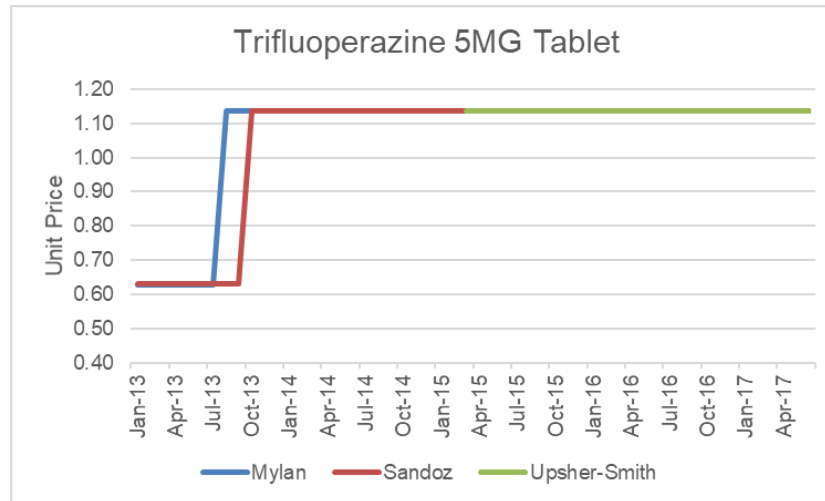
#### **14. Trifluoperazine HCL**

334. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for trifluoperazine HCL, used to treat schizophrenia. Senior executives, including Bresch, entered into the agreement and maintained compliance with it. On information and belief, all of the Top Executives were aware of this agreement, which has remained in effect until the present.

335. As shown below in Figure 14, during the Relevant Period, the price at which Mylan sold trifluoperazine HCL skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure 14 shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of trifluoperazine HCL.

336. Pricing for trifluoperazine HCL had for years remained stable, as is typical in a mature market. However, as shown in Figure 14, the price of trifluoperazine HCL charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

337. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure 14: Trifluoperazine HCL**

338. The magnitude by which Mylan and other marketers of trifluoperazine HCL increased the price of this drug is likewise telling. The average price of common dosages trifluoperazine HCL, as measured by NADAC data, increased by between 213% and 232% during the Relevant Period, and the average price of common dosages of trifluoperazine HCL increased by between 62% and 188% in a matter of days at some point during the Relevant Period.

339. Table 14 below displays percentage increases in NADAC data for common dosages of trifluoperazine HCL. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on trifluoperazine HCL – price hikes in which Mylan was an active and voluntary participant – were sudden and astronomical.



**Table 14: Trifluoperazine HCL**

<b>Drug Name and Form</b>	<b>Date of Largest % Increase in NADAC</b>	<b>Largest % Increase in NADAC</b>	<b>Lowest to Highest % Increase - LOWEST DATE</b>	<b>Lowest to Highest % Increase - HIGHEST DATE</b>	<b>Lowest to Highest % Increase</b>
Trifluoperazine 1 mg Tablet	2014-01-22	188%	2013-04-18	2014-01-22	223%
Trifluoperazine 2 mg Tablet	2013-12-18	181%	2013-11-21	2015-03-18	213%
Trifluoperazine 5 mg Tablet	2013-12-18	109%	2013-03-21	2015-03-18	229%
Trifluoperazine 10 mg Tablet	2013-12-18	62%	2013-04-18	2016-09-21	232%

**F. Mylan's Price Increases on Generic Drugs Would Have Been Against Its Self-Interest in the Absence of Price Collusion**

340. Mylan's price increases on generic drugs, including but not limited to the Price-Fixed Drugs, would have been against its self-interest in the absence of price collusion. Generic drugs, including the Price-Fixed Drugs, are a commodity, with any generic drug substitutable for another and differentiated competitively with each other primarily based on price. In a market free of collusion, if one generic drug marketer raises its prices significantly above those of its competitors, that marketer will lose market share. Yet, as explained above, Mylan and other drug marketers increased the prices of numerous generic drugs substantially during the Relevant Period.

**G. Mylan and Teva Conspired to Fix the Prices of Generic Drugs**

341. Certain details concerning how Mylan conspired with one of its co-conspirators, Teva, to fix the prices of generic drugs, are already clear.

342. Nisha Patel worked as a Director for Strategic Customer Marketing and a Director of National Accounts at Teva. Immediately after she began at Teva, Patel began to investigate Mylan drugs as a potential source for coordinated price increases. For example, on May 6, 2013, as she was creating the list of candidates, Patel sent Kevin Green at Teva an e-mail with an attached spreadsheet. Patel asked Green for certain specific items she had highlighted in blue, including nine Mylan drugs: tolmetin sodium capsules; doxazosin mesylate tablets; methotrexate tablets; diltiazem

HCL tablets; flurbiprofen tablets; nadolol tablets; amiloride HCL/HCTZ tablets; cimetidine tablets; and estradiol tablets.

343. The next day, May 7, 2013, Green spoke to Nesta at Mylan three times, including one call lasting more than 11 minutes. Green also called Patel twice that day to report on what he had learned. Green and Nesta also spoke a number of times over the next several days, including on May 8 (3:46 minutes), May 9 (4:05 minutes) and May 10, 2013 (0:28, 10:46 and 2:19 minutes).

344. On May 14, 2013, Patel asked several Teva national account managers, including Green, to obtain information on certain Mylan drugs, including cimetidine and nadolol, in preparation for a potential price increase. On May 17, 2013, Green spoke to Nesta six times, including calls lasting 11:50, 2:23, 4:25 and 16:02 minutes.

345. On May 29, 2013, after a discussion with Maureen Cavanaugh, Senior Vice President and Commercial Officer, North America at Teva, Patel added four Mylan drugs to the Teva price increase list: nadolol, cimetidine, prazosin, and methotrexate.

346. Discussions between Green and Nesta about specific drugs continued into June 2013, as Mylan was also preparing for major price increases on a number of its own drugs. From June 24 through June 28, 2013, for example, Green and Nesta had at least the following telephone calls:

Date	Call Type	Target Name	Direction	Contact Name	Time	Duration
6/24/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	13:25:29	0:00:06
6/24/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	13:32:25	0:10:13
6/25/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	13:43:27	0:00:06
6/25/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	16:02:58	0:00:32
6/25/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	16:51:43	0:00:03
6/26/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	9:55:29	1:00:25
6/27/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	10:47:23	0:00:06
6/27/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	11:04:04	0:01:03
6/27/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	15:42:07	0:04:20
6/28/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	10:59:56	0:03:53

347. On June 26, 2013, in the midst of this flurry of communications between Teva and Mylan (and the same day that Green and Nesta had a one-hour phone call), one of Patel's colleagues sent her a suggestion with the following list of potential drugs to add to the price increase list:

<u>Product</u>	<u>Competitors (Mkt Share)</u>
Disopyramide Phosphate Capsules	Actavis (61%)
Ketorolac Tablets	Mylan (32%)
Ketoprofen Capsules	Mylan (63%)
Hydroxyzine Pamoate Capsules	Sandoz (39%); Actavis (9%)
Nystatin Tablets	Heritage (35%); Mutual (32%)

Patel responded favorably with regard to some of the drugs, alluding to the fact that she had inside information about at least ketoprofen. At that time, nystatin was not considered a strong candidate for a price increase because of the quality of the competitors in the market. Those dynamics would later change after Patel struck up a collusive relationship with a high-level executive at Heritage.

348. Mylan raised its price for both ketorolac and ketoprofen (the two Mylan drugs on the list above) six days later, on July 2, 2013. Teva then quickly followed with its own price increases for both drugs (and others) on August 9, 2013. Those price increases were closely coordinated and agreed to by Teva and Mylan.

349. At the end of the flurry of phone communications between Teva and Mylan described above, on June 28, 2013, Green and Nesta had a four-minute call starting at 10:59 a.m. Within minutes after that call, Patel circulated an e-mail internally containing information obtained directly from Green, but got one significant point wrong (which confirms that she had advance notice of the Mylan increase). In actuality, Mylan did not announce the price increase until the following Monday, July 1, 2013 – with an effective date of July 2, 2013.

350. Patel consistently used a code word in e-mails to camouflage the fact that she and her co-conspirators within Teva were communicating with competitors about future price increases. She used the code word when discussing Taro in a May 24, 2013 spreadsheet relating to pricing, after

speaking with Aprahamian and before Taro raised its price on adapalene gel. She used it again on June 26, 2013 – after Green and Nesta spoke several times in advance of Mylan’s price increase on ketoprofen.

351. Similarly, on July 2, 2013 – the day before Teva’s price increases (including for the drug methotrexate) went into effect – a colleague asked Patel how Teva’s competitors’ pricing compared with regard to methotrexate. Patel responded that Mylan’s pricing was a little low on that drug, so Teva felt comfortable increasing the price of that drug on July 3, 2013. These predictions – which were based on the direct communications between Green and Nesta noted above – again turned out to be accurate: Mylan increased its price of methotrexate, pursuant to its agreement with Teva, on November 15, 2013.

352. Teva and Mylan continued to conspire to raise prices together. Teva and Mylan were coordinating price increases consistently during this period, including the time leading up to price increases on August 9, 2013. During each step in the process, Teva and Mylan executives kept their co-conspirators apprised of their decisions. The communications were typically initiated by Patel, who asked Green to communicate with Nesta and obtain Mylan’s position on many different drugs. But at times, Patel communicated directly with Nesta.

353. For example, on July 22, 2013, Patel sent Green an e-mail with an attached spreadsheet of pricing increase items. A large majority were Mylan drugs.

354. The next day – July 23, 2013 – at 4:30 p.m., Green and Nesta spoke for more than six minutes. Immediately after hanging up the phone, Green called Patel to convey the market intelligence he had obtained from Mylan. The call lasted more than three minutes.

355. On July 29, 2013, Green at Teva was approached by a large retail pharmacy asking for bids on several of the drugs that Mylan had increased prices on in early July. Green’s first step

was to request market share information for those drugs so that Teva could make a decision on how to respond to the customer's inquiry based on the generally accepted understanding regarding fair share.

356. The next day, July 30, 2013, Patel sent Green the price increase file as an attachment. Patel asked Green to obtain additional information for a group of Mylan drugs, some of which varied slightly from the prior spreadsheet.

357. Following the same consistent pattern, Green and Nesta spoke six times over the next two days. After hanging up from the last call between him and Nesta on August 1, 2013, Green called Patel and conveyed the results of his conversations. This series of phone calls is detailed below.

Date	Call Type	Target Name	Direction	Contact Name	Time	Duration
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:10:33	0:04:52
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:50:57	0:01:09
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:54:39	0:03:21
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:59:57	0:06:53
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	16:46:59	0:01:27
8/1/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	11:23:47	0:05:48
8/1/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	12:21:43	0:00:59
8/1/2013	Voice	Patel, Nisha (Teva)	Incoming	Green, Kevin (Teva)	12:29:55	0:02:36

358. In the midst of the phone calls between Green and Nesta on July 31, 2013, Patel sent an e-mail concerning a customer request, with a particular focus on balancing Teva's desire to increase prices against its commitment to adhere to the fair share agreement, as well as how that may affect Teva's market share for certain products sold by Mylan.

359. Based on all these communications between Mylan and Teva (and at times other competitors), Mylan and Teva successfully increased the prices on seven different drugs on August 9, 2013.

360. Effective April 17, 2014, Mylan increased its Wholesale Acquisition Cost, or WAC, pricing on a number of different drugs, including several that overlapped with Teva. Mylan also increased its contract prices, but at least some of those price increases would not become effective until mid-May 2014. Pursuant to the established understanding between the two companies, Teva immediately decided that it would follow the Mylan increases. On April 21, 2014, T.S., a national account executive at Teva, forwarded to Patel two spreadsheets with average wholesale price and WAC pricing information for the price increases taken by Mylan. The spreadsheets were created by Mylan personnel. Patel, in turn, forwarded the e-mail to the Teva sales team. Patel's e-mail referenced a list that included the following products, several of which had been the subject of coordinated price increases in 2013 as well: amiloride HCL/HCTZ tablets; cimetidine tablets; enalapril maleate tablets; fluvastatin sodium capsules; loperamide HCL capsules; prazosin HCL capsules; and sotalol hydrochloride tablets. Within days, Teva began receiving requests from its customers for bids due to the Mylan price increases. On April 24, 2014, Patel began to formulate a response to those requests, but noted that Teva was aware of the Mylan customer contract price points, which were not publicly available. Previously, Patel had relied on Kevin Green to obtain specific Mylan customer price points through his communications with Nesta, which she used to follow Mylan's pricing. The next day, in a follow-up e-mail about the Mylan strategy, Patel noted that one of her Mylan increase strategies would not have been appropriate for this situation.

361. Patel continued to push for specific contract price points from Mylan. On April 28, 2014, Patel sent an e-mail to the Teva sales team. On May 9, 2014, Patel sent another e-mail to Rekenthaler. Shortly after receiving that e-mail – at 11:15 a.m. that morning – Rekenthaler called Nesta and left a message. Nesta returned the call at 11:23 a.m. and the two spoke for nearly eight minutes.



362. Separately, and before Rekenthaler was able to convey any information he had obtained, Patel forwarded a customer request from ABC (relating to the Mylan price increase items) directly to T.S. at Teva, lamenting the absence of Green to obtain intelligence about Mylan. The next day, T.S. sent Patel an e-mail with an attached spreadsheet listing the Mylan contract price points for all of the recent increases. The spreadsheet attached to the e-mail was created by a Mylan employee.

363. Rekenthaler and Nesta spoke again on May 20, 2014. Patel was more confident that Teva could follow the Mylan price increases exactly, without disrupting the market. That same day, as Patel began to create a new list of Teva price increase candidates, she instructed a colleague to include the Mylan price increase drugs – with specific price points – as its own separate tab in the spreadsheet, called “follow.” Her colleague provided the list, as requested, on May 21, 2014.

364. On May 27, 2014, Rekenthaler and Nesta spoke twice, including one call lasting nearly four minutes. By May 28, 2014, Teva had a much more comprehensive list of price increase items. On that list, seven of the Mylan items were prominently listed.

365. Also on the list were three additional Mylan drugs for which Teva would be leading the price increase: diclofenac potassium tablets, flurbiprofen tablets, and prochlorperazine tablets. With the list firmly squared away at the end of May, Rekenthaler and Nesta had no need to speak again until August, when Teva was preparing to implement the price increases. In the weeks leading up to the August 28, 2014 Teva price increases, Rekenthaler and Nesta spoke several times to coordinate, including at least the calls set forth below:

Date	Call Type	Target Name	Direction	Contact Name	Duration
8/4/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:01:00
8/4/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:06:00
8/7/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:14:00
8/11/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:02:00
8/11/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:06:00
8/18/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:01:00
8/18/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:13:00
8/21/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:06:00

366. Representatives from Mylan, Teva, Sandoz, and various other generic drug manufacturers met in Boston, Massachusetts from August 23-26, 2014 for the National Association of Chain Drug Stores annual event, which was the largest pharmaceutical industry meeting of the year.

**H. Mylan's Co-Conspirator Teva Considered Mylan to Be Its "Highest Quality" Competitor, i.e., the Company Most Willing to Conspire to Fix Prices**

367. In 2013, Nisha Patel at Teva decided to rank generic drug manufacturers by their willingness to conspire to fix the prices of generic drugs. By May 6, 2013, Patel had completed an initial ranking of 56 different manufacturers in the generic drug market by their "quality." Patel defined "quality" by her assessment of the "strength" of a competitor as a leader or follower for price increases. Ranking was done numerically, from a +3 ranking for the "highest quality" competitor to a -3 ranking for the "lowest quality" competitor.

368. Patel created a formula, which heavily weighted those numerical ratings assigned to each competitor based on their "quality," combined with a numerical score based on the number of competitors in the market and certain other factors. According to her formula, the best possible candidate for a price increase would be a drug where there was only one other competitor in the market, which would be leading an increase, and where the competitor was the highest "quality." Conversely, a Teva price increase in a drug market with several "low quality" competitors would not



be a good candidate due to the potential that those low quality competitors might not follow Teva's price increase and might instead use the opportunity to steal Teva's market share. Notably, the companies with the highest rankings at this time were companies with whom Patel and other executives within Teva had significant relationships.

369. The highest quality competitors in Patel's rankings were competitors with whom Teva had agreements to lead and follow each other's price increases. The agreements and understandings regarding price increases were what made each of those competitors a high quality competitor. As part of their understandings, those competitors also agreed that they would not seek to compete for market share after a Teva price increase.

370. Mylan was Teva's highest ranked competitor by "quality." The relationship between these two competitors was longstanding and deeply engrained. It survived changes in personnel over time and pre-dated Patel's creation of the quality competitor rankings. Kevin Green, who was employed by Teva beginning in 2006 through late October 2013, first began communicating with Mylan's Nesta by telephone on February 21, 2012. From that time until the time that Green left Teva, Green and Nesta were in almost constant communication, speaking by phone at least 392 times and exchanging at least 12 text messages – including at or around every significant price increase taken by either company. This amounts to an average of nearly one call or text message every business day during this period.

371. Shortly after Patel started her employment at Teva, she called Nesta on May 10, 2013 and the two spoke for over five minutes. Because Green had already established a relationship with Mylan, Patel did not need to speak directly with Nesta very often. Typically, Patel would e-mail Green and ask him to obtain market intelligence about certain Mylan drugs; Green would then speak to Nesta – often about a long list of drugs – and report his findings back to Patel. When Green left

Teva to join Zydus Pharmaceuticals (USA), Inc. in late October 2013, the institutional relationship and understanding between Teva and Mylan remained strong. David Rekenthaler promptly took over the role of communicating with Nesta. Starting in December 2013, through the time that Rekenthaler left Teva in April 2015, Rekenthaler spoke to Nesta 100 times. Prior to Green leaving Teva in late-October 2013, Rekenthaler and Nesta had only spoken by phone once, more than a year earlier in 2012.

# **I. The Structure of the Generic Drug Market Facilitated Mylan's Collusion**

372. From at least 2013 to the present, the market structure for the Price-Fixed Drugs was highly conducive to the formation and maintenance of a price-fixing conspiracy. Publicly available data on the markets for the Price-Fixed Drugs in the United States demonstrate that each is susceptible to cartelization by Mylan and other generic drug marketers. Factors that make the markets for the Price-Fixed Drugs highly susceptible to collusion include: (1) a high degree of industry concentration; (2) high barriers to entry; (3) demand inelasticity; (4) the lack of available substitutes; (5) a high degree of interchangeability among co-conspirators' generic versions of the same drugs; (6) ease of information sharing and opportunities for intercompetitor contacts and communication; (7) sufficient numbers to drive competition; (8) absence of departures from the market; (9) absence of non-conspiring competitors; (10) size of price increases; and (11) reimbursement of generic drugs.

## **1. High Degree of Industry Concentration**

373. The markets for the Price-Fixed Drugs are highly concentrated and each is dominated by a handful of companies.

374. The commonly accepted measure of market concentration is the Herfindahl-Hirschman Index ("HHI"). The HHI is calculated by squaring the market share of each firm

competing in the market and then summing the resulting numbers. For example, for a market consisting of three firms with shares of 20%, 30%, and 50%, the HHI is 3,800. Federal antitrust enforcement agencies consider markets in which the HHI is above 2,500 to be highly concentrated. In merger reviews, for instance, a proposed merger that would lead to a highly concentrated market, and an increase in the HHI of more than 200 points, creates a presumption of market power and a recognized risk of collusion. Throughout the Relevant Period, the HHI for some or all of the Price-Fixed Drugs was at a level that antitrust enforcement agencies consider indicative of a highly concentrated market vulnerable to collusion.

375. Concentration facilitates collusion because it reduces the number of negotiating partners and increases per-firm collusive profits. Concentration also significantly increases the stability of a cartel. One of the primary difficulties cartels face is cheating: each member has an individual incentive to lower prices slightly below the cartel price to capture significant market share. In a concentrated market, cheating is more easily prevented because each member of the cartel may more easily monitor the others and enforce compliance. In addition, as the number of firms in a market decreases, the probability decreases that firms have different costs and differentiated products, which facilitates cartel formation and maintenance.

## **2. High Barriers to Entry**

376. The presence of significant barriers to entry facilitates the operation of a cartel. Barriers to entry increase a market's susceptibility to a coordinated effort to maintain supracompetitive prices because it is difficult for new suppliers to enter the market and destabilize coordinated supracompetitive prices.

377. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the markets for the Price-Fixed Drugs. As the dominant players in

this market, defendants were able to fix, raise, and maintain Mylan's prices for the Price-Fixed Drugs without competitive threats from rival generic drug manufacturers.

### **3. Demand Inelasticity**

378. Price elasticity of demand is defined as the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. It is a measure of how demand for a product reacts to a change in price. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

379. For a cartel to profit from raising prices above competitive levels, demand for the product must be relatively inelastic such that any loss in sales will be more than offset by increases in revenue on those sales that are made. Otherwise, increased prices would result in declining sales, revenues, and profits, as customers purchase substitute products or decline to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

380. The Price-Fixed Drugs are critical to the health of patients; they are considered medical necessities that must be purchased at whatever cost the defendants offer them for sale. Thus, the Price-Fixed Drugs are excellent candidates for cartelization, because price increases will result in more revenue, rather than less.

381. The Price-Fixed Drugs are necessary for the treatment of millions of patients for which no substitute drugs are available. The Price-Fixed Drugs are thus particularly susceptible to collusive price-fixing, as price increases will not result in such a loss of sales so as to reduce profits, but instead will result in more profits for cartel members.

**4. Lack of Available Substitutes**

382. Many patients are unable to substitute other medications for the Price-Fixed Drugs. In some cases, the Price-Fixed Drugs are the only effective treatment for their conditions.

**5. High Degree of Interchangeability of Generic Drug Products**

383. A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitution among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers to agree on prices for the goods in question and it is easier to monitor these prices effectively.

384. The Price-Fixed Drugs are commodity products. Therefore, the products are interchangeable, as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, each drug manufacturer had to raise prices for the cartel to succeed. Indeed, as explained above, Mylan raising its prices for the Price-Fixed Drugs was against its individual economic interest, because its supposed competitors could have priced the drugs below Mylan's prices and won substantial market share.

**6. Ease of Information Sharing and Opportunities for Contacts and Communications Among Competitors**

385. Mylan and other participants in the cartel communicated their present and future pricing decisions to each other, including in public settings such as earnings calls. By design, Mylan knew what the other cartel participants charged for their generic products, and what each was going to charge in the future. Price transparency and communications ensured that Mylan and other cartel members could monitor compliance with the cartel, and provided a mechanism by which each could assure the others that they would keep up their end of the bargain.

386. Mylan and other cartel participants are members of the same trade association: the Generic Pharmaceutical Association (“GPhA”) (now known as the Association for Accessible Medicines). Senior executives of Mylan participate actively in the GPhA. For instance, Bresch served as chair of GPhA’s board of directors during the Relevant Period. Representatives of Mylan and other cartel members met in person at GPhA meetings before and during the Relevant Period, including immediately before certain price increases for the Price-Fixed Drugs were announced. The following table shows GPhA meetings at which Mylan was in attendance and the dates and locations of these meetings.

<b>Meeting</b>	<b>Meeting Date &amp; Location</b>
2012 GPhA Annual Meeting	February 22-24, 2012 Orlando, Florida
2012 GPhA Fall Technical Conference	October 1-3, 2012 Bethesda, Maryland
2013 GPhA Annual Meeting	February 20-22, 2013 Bethesda, Maryland
2013 GPhA CMC Workshop	June 4-5, 2013 Bethesda, Maryland
2013 GPhA Fall Technical Conference	October 28-30, 2013 Bethesda, Maryland
2014 GPhA Annual Meeting	February 19-21, 2014 Orlando, Florida

387. These in-person meetings provided additional opportunities to collude. As 46 state attorneys general (the “AGs”) have now alleged: these trade shows “provide generic drug manufacturers . . . with ample opportunity to meet, discuss, devise, and implement a host of anticompetitive schemes that unreasonably restrain competition.”

388. Mylan and other generic drug companies use other industry trade shows and customer conferences to collude, including conferences hosted by the National Association of Chain Drug Stores, Healthcare Distributions Management Association or HDMA (now known as the Healthcare

Distribution Alliance), and Efficient Collaborative Retail Marketing, among others. The AGs have alleged further:

At these various conferences and trade shows, sales representatives from many generic drug manufacturers . . . have opportunities to interact with each other and discuss their respective businesses and customers. Attendant with many of these conferences and trade shows are organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors outside of the traditional business setting. Of particular importance here, generic drug manufacturer representatives who attend these functions, . . . use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

389. The AGs also have alleged that sales representatives of generic drug manufacturers “get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business.” “In fact, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as ‘industry dinners.’” “At these industry dinners, one company is usually responsible for paying for dinner for all of the attendees. The company that pays the bill is generally determined by alphabetical order.”

## **7. Sufficient Numbers to Drive Competition**

390. While the markets for the Price-Fixed Drugs had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with competitive generic pricing and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near-direct cost levels. With the number of generic competitors in the market, historical fact and accepted economics teach that, absent collusion, prices would remain at competitive levels.

## **8. Absence of Departures from the Market**

391. There were no departures from the markets for the Price-Fixed Drugs that could explain the price increases.

### **9. Absence of Non-Conspiring Competitors**

392. Defendants have maintained supracompetitive pricing for the Price-Fixed Drugs throughout the Relevant Period. Thus, defendants have oligopolistic market power in the markets for the Price-Fixed Drugs, enabling price increases without loss of market share to non-conspirators. Indeed, no competitors not part of the conspiracy have emerged to undercut the defendants' supracompetitive pricing.

### **10. Size of Price Increases**

393. The magnitude of the price increases involved further differentiates them from parallel price increases. Oligopolists seeking to test market increases need to take measured approaches. But here the increases are not 5% or even 10% jumps – the increases are, in just one act, more than 200 times the current price of the product. A rational oligopolist, when unaided with the certainty that its ostensible competitors would follow, would not do so.

### **11. Reimbursement of Generic Drugs**

394. This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by maximum allowable cost pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, the usual inhibition of an oligopolist to unilaterally raise prices is embedded in the generic reimbursement system. In the absence of coordinated pricing activity among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales. However, when one observes significant price increases – particularly those of the kind alleged here – basic market economics dictate that the generic drug makers likely have an



expectation that they would not lose volume (based on their expectations of what their ostensible competitors would do), because they colluded.

**J. Mylan Misled Investors About the Competition It Faced and Validity of Its Sales**

395. Mylan repeatedly stated that the generic drug market is highly competitive. Mylan's statements about the highly competitive nature of the generic drug market were misleading to the extent that Mylan failed to state that the market for generic drugs had been allocated between competitors and that the prices for drugs had been fixed at supracompetitive levels.

396. Mylan also made numerous statements regarding its sales of drugs and its related financial performance. Mylan's statements about its sales were misleading to the extent these figures were based on fixed prices, rather than prices dictated by market forces – investors believed these figures to be based on Mylan's performance in competitive markets, when in fact they were not.

397. These and Mylan's numerous other misleading statements relating to Mylan's market allocation and price-fixing activity are detailed in §VII, *infra*.

**K. The DOJ, SEC, Congress, and the States Have Responded to the Massive Increases in the Prices of Generic Drugs, Including the Price-Fixed Drugs**

398. Mylan's dramatic and unexplained hikes in the prices of the Price-Fixed Drugs and other drugs have given rise to extensive scrutiny by the U.S. Congress and by federal and state antitrust regulators.

399. In a January 8, 2014 letter to members of key committees of the U.S. House of Representatives and Senate, Douglas P. Hoey, CEO of the NCPA, asked Congress to conduct an investigation of generic drug price increases.

400. In July 2014, the attorneys general of 20 states, including the Attorney General of Connecticut, began a wide-ranging investigation into the pricing of generic drugs by generic drug companies, including Mylan.

401. On October 2, 2014, Representative Elijah E. Cummings (“Cummings”), Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernie Sanders (“Sanders”), Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, sent letters to drug manufacturers, including Mylan, asking for detailed information on the generic price hikes.

402. On November 20, 2014, Senator Sanders’s committee held a hearing entitled “Why Are Some Generic Drugs Skyrocketing in Price?” Various witnesses discussed the price hikes for generic drugs.

403. By November 2014, the DOJ commenced a wide-ranging criminal investigation of generic drug pricing and caused grand jury subpoenas to be issued to various generic drug manufacturers, including Mylan, in connection with this investigation.

404. On February 24, 2015, Sanders and Cummings wrote a letter to the Office of the Inspector General (“OIG”) of HHS, asking it to investigate the effects that price increases of generic drugs have had on generic drug spending within the Medicare and Medicaid programs. The OIG responded in a letter dated April 13, 2015, stating it planned to engage in a review of quarterly average manufacturer prices for the 200 top generic drugs from 2005 through 2014.

405. In December 2015, the DOJ issued a subpoena to Mylan and certain of its employees and senior management relating to the marketing of some of Mylan’s generic products, as well as “any communications with competitors about such products.” Related search warrants were executed in connection with the DOJ’s investigation. The DOJ probes were initially focused on two

generic drugs: digoxin and doxycycline. News reports have confirmed the DOJ's investigation is significantly broader and encompasses as many as a dozen generic drug manufacturers and is examining a conspiracy to fix, raise, maintain, and stabilize the prices of as many as two dozen generic drugs, including the Price-Fixed Drugs. Moreover, these reports suggest that a leniency applicant came forward during the summer of 2016 and is working with the DOJ in its ongoing investigation.

406. The DOJ investigation could result in the imposition of substantial fines and criminal pleas for Mylan and jail time for Mylan executives. Some analysts have estimated that Mylan could face liability of between \$380 million and \$770 million in fines and that the DOJ could impose industry-wide fines in excess of \$1 billion.<sup>39</sup>

407. Also, in December 2015, Mylan received a subpoena from the Attorney General of Connecticut regarding the price and marketing of doxycycline.

408. On December 14, 2016, the attorneys general of twenty states, including the Attorney General of Connecticut, filed a civil case against six generic drug manufacturers, including Mylan. The States allege that their investigation, which is still ongoing, "uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States." The States' "initial civil action" concerned two generic drugs: Doxy DR and glyburide. The States have made clear that the evidence of wrongdoing they have uncovered extends far beyond the defendants and drugs identified in their "initial civil action." The Attorney General of Connecticut, George C. Jepson, whose office led the States' antitrust investigation, told *The New York Times*: "We believe that this is just the tip of the

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<sup>39</sup> Eric Sagonowsky, *DOJ's Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says*, FiercePharma (Nov. 10, 2016), <http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says>.

iceberg. . . . I stress that our investigation is continuing, and it goes way beyond the two drugs in this lawsuit, and it involves many more companies than are in this lawsuit.”

409. Also on December 14, 2016, the DOJ brought felony charges against two former senior generic pharmaceutical executives for their roles in conspiracies to fix prices, rig bids, and allocate customers for generic drugs. The DOJ alleged that Jeffrey Glazer, the former CEO of Heritage, and Jason Malek, the former President of Heritage, conspired to fix prices, rig bids, and allocate customers for Doxy DR. The DOJ also alleged that Glazer and Malek conspired to fix prices and allocate customers for glyburide, a medicine used to treat diabetes. This conspiracy included Mylan executives. The DOJ alleged that the “doxycycline hyclate conspiracy” began in approximately April 2013 and continued until at least December 2015.

410. On January 9, 2017, Glazer and Malek pled guilty to felony charges that they conspired with competitors to manipulate prices and allocate customers for Doxy DR. Glazer admitted that:

[He] participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products including Doxycycline Hyclate, the primary purpose of which was to allocate customers, rig bids and fix and maintain prices of Doxycycline Hyclate sold in the United States in furtherance of the conspiracy.

Defendant and his co-conspirators, including individuals that the defendant supervised at his company and those he reported to at his company’s parent, engaged in discussions and attended meetings with the co-conspirators involved in the production and sale of Doxycycline Hyclate. During such discussions and meetings, agreements were reached to allocate customers, rig bids and fix and maintain the prices of Doxycycline Hyclate sold in the United States.<sup>40</sup>

Malek admitted substantially the same facts.<sup>41</sup>

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<sup>40</sup> Tr. of Plea Hearing at 19:16-20:4, *United States v. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id.* at 22:4-11 (admitting facts).

<sup>41</sup> Tr. of Plea Hearing at 19:12-20:1, *United States v. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id.* at 21:23-22:6 (admitting facts).

411. On May 10, 2019, the attorneys general of over 40 states filed a new antitrust action against Mylan and other generic drug companies in the U.S. District Court for the District of Connecticut. *See* Complaint, *State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (D. Conn. May 10, 2019). The complaint alleges an industry-wide conspiracy that included Mylan, in which competitors were expected to receive their “fair share” of the market – whether for a particular generic drug or multiple generic drugs – and were expected to “play nice in the sandbox” so as not to undercut the other participants in the conspiracy. *Id.* at ¶¶ 114-115, 137. The complaint further alleges that executives at Mylan expressly agreed with other drug companies in specified calls and other communications to allocate the market for, and to fix the prices of, numerous generic drugs – activity involving virtually the entire generic drug industry.

## **VII. DEFENDANTS’ FALSE AND MISLEADING STATEMENTS**

### **A. Defendants’ False and Misleading Statements in 2012**

412. On February 21, 2012, Mylan filed an Annual Report on Form 10-K with the SEC reporting the Company’s financial and operating results for the quarter and year ended December 31, 2011 (the “February 21, 2012 10-K”). For the quarter, Mylan reported net income of \$129.49 million, or \$0.30 per diluted share, on revenue of \$1.53 billion, compared to net income of \$19.85 million, or \$0.01 per diluted share, on revenue of \$1.43 billion for the same period in the prior year. For 2011, Mylan reported net income of \$536.81 million, or \$1.22 per diluted share, on revenue of \$6.1 billion, compared to net income of \$345.12 million, or \$0.68 per diluted share, on revenue of \$5.4 billion for 2010. The February 21, 2012 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by CEO Bresch and CFO Sheehan stating that the financial information contained in the February 21, 2012 10-K was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

413. The February 21, 2012 10-K stated, in relevant part:

Gross profit for the current year was \$2.56 billion and gross margins were 41.8%. For 2010, gross profit was \$2.22 billion, and gross margins were 40.7%. Gross profit for the current year is impacted by purchase accounting and other special items recorded during 2011, of approximately \$373.2 million, which consisted primarily of amortization related to purchased intangible assets associated with acquisitions. Excluding such items, gross margins would have been approximately 48%. Prior year gross profit is also impacted by similar purchase accounting and other special items in the amount of \$315.9 million. Excluding such items, gross margins in the prior year would have also been approximately 47%. The increase in gross margins is primarily the result of new products launched in the North American region of our Generics segment and favorable pricing on the EpiPen Auto-Injector in our Specialty segment and the continued vertical integration and leveraging of our manufacturing platform.

414. The statements in ¶¶412-413 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases.

415. In the February 21, 2012 10-K, Mylan also stated:

*Specialty Segment*

\* \* \*

The EpiPen Auto-Injector is the number one prescribed . . . auto-injector with more than 95% market share in the U.S. and . . . worldwide . . . . The strength of the EpiPen brand name, quality and ease of use of the product and the promotional strength of the Dey U.S. sales force have enabled us to maintain our market share.

\* \* \*

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from***

*15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.* We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.<sup>42</sup>

416. The statements in ¶415 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

417. In the February 21, 2012 10-K, Mylan also stated:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

\* \* \*

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .

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<sup>42</sup> The risk disclosures in each of Mylan's annual reports filed during the Relevant Period were incorporated by reference into each of the subsequent quarterly reports filed by Mylan during the following year. In stating in each of its quarterly reports that no material changes had occurred to the disclosures that had been made, Mylan made the same misleading statements in each quarterly report during the Relevant Period that it made in the annual reports preceding them. Emphasis has been added throughout unless otherwise noted.

[S]hould there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken . . . .

418. The statements in ¶417 were misleading because they fail to disclose that: (1) Mylan had in fact already failed to comply with its “reporting and payment obligations under the . . . Medicaid Rebate Program”; (2) classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan’s classification of the EpiPen was not subject to a “risk of error[,]” as that risk of error had already materialized; (4) Mylan’s classification of the EpiPen was not subject to differing interpretations, as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; and (5) a government authority had already taken a position “with regard to how to properly calculate . . . payments” that was “contrary to a position [Mylan had] taken,” as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination.

419. On April 26, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2012 (the “April 26, 2012 8-K”). For the quarter, Mylan reported net income of \$129.1 million, or \$0.30 per diluted share, on revenue of \$1.58 billion, compared to net income of \$104.2 million, or \$0.23 per diluted share, on revenue of \$1.45 billion for the same period in the prior year. In the April 26, 2012 8-K, Mylan stated, in relevant part:

For the quarter ended March 31, 2012, Mylan’s Specialty segment reported third party net revenues of \$162.3 million, an increase of \$65.3 million, or 67.3%, from the comparable prior year period of \$97.0 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN<sup>®</sup> auto-injector, sales of which increased as a result of favorable pricing and growth in both the overall market and Mylan’s market share. The EPIPEN<sup>®</sup> auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions and maintains a market share in excess of 95% in the United States.



Gross profit for the quarter ended March 31, 2012 was \$666.3 million and gross margins were 41.8%. In the comparable prior year period, gross profit was \$590.9 million, and gross margins were 40.8%. Adjusted gross profit for the quarter ended March 31, 2012 was \$760.0 million and adjusted gross margins were 48% as compared to adjusted gross profit of \$681.8 million and adjusted gross margins of 47% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America and favorable pricing on the EPIPEN<sup>®</sup> auto-injector, partially offset by the impact of pricing reductions in all regions of our generics segment.

420. The statements in ¶419 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases.

421. In its April 27, 2012 Quarterly Report on Form 10-Q, Mylan stated:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .

\* \* \*

[S]hould there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken . . . .

422. The statements in ¶421 are misleading because they fail to disclose that: (1) Mylan had in fact already failed to comply with its “reporting and payment obligations under the . . . Medicaid Rebate Program”; (2) classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan’s classification of the EpiPen was not subject to a “risk of error[,]” as that risk of error had already materialized; (4) Mylan’s classification of the EpiPen was not subject to differing interpretations, as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; and (5) a government authority had already taken a position “with regard to how to properly calculate . . . payments” that was “contrary to a position [Mylan had] taken,” as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination.

423. On July 26, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company’s financial and operating results for the quarter ended June 30, 2012 (the “July 26, 2012 8-K”). For the quarter, Mylan reported net income of \$138.6 million, or \$0.33 per diluted share, on revenue of \$1.69 billion, compared to net income of \$146.4 million, or \$0.33 per diluted share, on revenue of \$1.57 billion for the same period in the prior year. In the July 26, 2012 8-K, Mylan stated:

For the current quarter, Mylan’s Specialty segment reported third party net sales of \$198.6 million, an increase of \$66.9 million, or 50.8%, from the comparable prior year period of \$131.7 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and growth in the overall market. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended June 30, 2012, was \$699.2 million and gross margins were 41.3%. For the three months ended June 30, 2011, gross profit was \$669.4 million, and gross margins were 42.5%. Adjusted gross profit, as further defined below, for the three months ended June 30, 2012 was \$819.2 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$758.7

million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of favorable volume and pricing on the EPIPEN® auto-injector and new products, partially offset by the impact of unfavorable pricing in all regions of our generics segment.

424. The statements in ¶423 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases.

425. In its July 26, 2012 Quarterly Report on Form 10-Q, Mylan stated:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .

\* \* \*

[S]hould there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken . . . .

426. The statements in ¶425 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its “reporting and payment obligations under the . . . Medicaid Rebate Program”; (2) classification of the EpiPen was not complex and did not involve

subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error[]," as that risk of error had already materialized; (4) Mylan's classification of the EpiPen was not subject to differing interpretations, as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; and (5) a government authority had already taken a position "with regard to how to properly calculate . . . payments" that was "contrary to a position [Mylan had] taken," as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination.

427. On October 25, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended September 30, 2012 (the "October 25, 2012 8-K"). For the quarter, Mylan reported net income of \$211.3 million, or \$0.51 per diluted share, on revenue of \$1.81 billion, compared to net income of \$156.7 million, or \$0.36 per diluted share, on revenue of \$1.58 billion for the same period in the prior year. In the October 25, 2012 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$294.1 million, an increase of \$80.1 million, or 37.4%, from the comparable prior year period of \$213.9 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and volume, including growth in the overall market. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended September 30, 2012, was \$788.5 million and gross margins were 43.6%. For the three months ended September 30, 2011, gross profit was \$658.4 million, and gross margins were 41.8%. Adjusted gross profit, as further defined below, for the three months ended September 30, 2012 was \$940.6 million and adjusted gross margins were 52% as compared to adjusted gross profit of \$763.9 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America and the increase in sales of the EPIPEN® auto-injector, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

428. The statements in ¶427 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases.

**B. Defendants' False and Misleading Statements in 2013**

429. On February 27, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2012 (the "February 27, 2013 8-K"). For the quarter, Mylan reported net income of \$162 million, or \$0.39 per diluted share, on revenue of \$1.72 billion, compared to net income of \$129.5 million, or \$0.30 per diluted share, on revenue of \$1.53 billion for the same period in the prior year. For 2012, Mylan reported net income of \$640.9 million, or \$1.52 per diluted share, on revenue of \$6.8 billion, compared to net income of \$536.8 million, or \$1.22 per diluted share, on revenue of \$6.13 billion for 2011. In the February 27, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$145.3 million, an increase of \$40.6 million, or 38.8%, from the comparable prior year period of \$104.7 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume, including growth in the overall market. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended December 31, 2012, was \$742.3 million and gross margins were 43.1%. For the three months ended December 31, 2011, gross profit was \$644.6 million, and gross margins were 42.1%. Adjusted gross profit, as further defined below, for the three months ended December 31, 2012 was \$845.4 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$732.2 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America during 2012 and the increase in sales of the EPIPEN® Auto-Injector, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

430. The statements in ¶429 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

431. In its February 28, 2013 Annual Report on Form 10-K, Mylan stated, in relevant part:

*Specialty Segment*

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory, severe allergy and psychiatry markets. Mylan Specialty's portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Mylan Specialty's revenues are derived through the sale of the EPIPEN® Auto-Injector.

The EPIPEN® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EPIPEN® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EPIPEN® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our market share.

\* \* \*

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The

Patient Protection and Affordable Care Act (the “PPACA”) and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. *The required rebate is currently 13% of the average manufacturer’s price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer’s price or the difference between the average manufacturer’s price and the best price during a specific period.* We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

432. The statements in ¶431 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer’s price for sales of Medicaid-reimbursed products.

433. In the February 28, 2013 10-K, Mylan stated, in relevant part:

### **Competition**

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded products that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:

*United States.* The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio offering size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty Segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.



Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty Segment business, our competitors include branded manufacturers who offer products for the treatment of COPD, severe allergies and major depressive disorder, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

434. The statements in ¶433 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by engaging in anticompetitive conduct to eliminate competitors of the EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and pharmacy benefits managers contingent upon excluding Sanofi's Auviqu from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anticompetitive conduct "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel in which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

435. In the February 28, 2013 10-K, Mylan stated, in relevant part:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY



DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies . . . .

\* \* \*

Any governmental agencies that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, ***should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken***, and may impose civil and/or criminal sanctions.

436. The statements in ¶435 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its “reporting and payment obligations under the . . . Medicaid Rebate Program”; (2) classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan’s classification of the EpiPen was not subject to a “risk of error[,]” as that risk of error had already materialized; (4) Mylan’s classification of the EpiPen was not subject to differing interpretations, as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; and (5) a government authority had already taken a position “with regard to how to properly calculate . . . payments” that was “contrary

to a position [Mylan had] taken,” as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination.

437. On May 2, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2013 (the “May 2, 2013 8-K”). For the quarter, Mylan reported net income of \$106.9 million, or \$0.27 per diluted share, on revenue of \$1.63 billion, compared to net income of \$129.1 million, or \$0.30 per diluted share, on revenue of \$1.58 billion for the same period in the prior year. In the May 2, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan’s Specialty segment reported third party net sales of \$211.6 million, an increase of \$40.6 million, or 23.7%, from the comparable prior year period of \$171.1 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions. In addition, Perforomist® Inhalation Solution sales increased by double digits from the comparable prior year period as a result of favorable pricing and volume.

Gross profit for the three months ended March 31, 2013, was \$693.5 million and gross margins were 42.5%. For the three months ended March 31, 2012, gross profit was \$670.2 million, and gross margins were 42.3%. Adjusted gross profit, as further defined below, for the three months ended March 31, 2013 was \$796.5 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$760.0 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of the increase in sales of the EPIPEN® Auto-Injector and margins on new products, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

438. The statements in ¶437 were misleading because they failed to disclose that Mylan’s net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix

the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

439. On August 1, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended June 30, 2013 (the "August 1, 2013 8-K"). For the quarter, Mylan reported net income of \$177.7 million, or \$0.46 per diluted share, on revenue of \$1.70 billion, compared to net income of \$138.6 million, or \$0.33 per diluted share, on revenue of \$1.69 billion for the same period in the prior year. In the August 1, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$236.9 million, an increase of \$30.3 million, or 14.7%, from the comparable prior year period of \$206.6 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended June 30, 2013, was \$742.4 million and gross margins were 43.6%. For the three months ended June 30, 2012, gross profit was \$702.6 million, and gross margins were 41.6%. Adjusted gross profit, as further defined below, for the three months ended June 30, 2013 was \$834.2 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$819.3 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of the increase in sales of the EPIPEN® Auto-Injector and margins on new products, which was offset the impact of unfavorable pricing on existing products in all regions within our Generics segment.

440. The statements in ¶439 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix

the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

441. On October 31, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended September 30, 2013 (the "October 31, 2013 8-K"). For the quarter, Mylan reported net income of \$158.9 million, or \$0.40 per diluted share, on revenue of \$1.77 billion, compared to net income of \$211.3 million, or \$0.51 per diluted share, on revenue of \$1.80 billion for the same period in the prior year. In the October 31, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net revenues of \$357.2 million, an increase of \$55.4 million, or 18.4%, from the comparable prior year period of \$301.8 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions. In addition, Perforomist® Inhalation Solution sales increased by double digits from the comparable prior year period as a result of favorable pricing and volume.

Gross profit for the three months ended September 30, 2013 was \$808.5 million, and gross margins were 45.7%. For the three months ended September 30, 2012, gross profit was \$793.1 million, and gross margins were 44.0%. Adjusted gross profit, as further defined below, for the three months ended September 30, 2013 was \$903.2 million and adjusted gross margins were 51% as compared to adjusted gross profit of \$940.5 million and adjusted gross margins of 52% in the comparable prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of the increase in sales of the EPIPEN® Auto-Injector and higher margins on products launched in 2013, which were more than offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment, including products launched in the prior year.

442. The statements in ¶441 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix

the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

**C. Defendants' False and Misleading Statements in 2014**

443. On February 27, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2013 (the "February 27, 2014 8-K"). For the quarter, Mylan reported net income of \$180.2 million, or \$0.45 per diluted share, on revenue of \$1.81 billion, compared to net income of \$162.0 million, or \$0.39 per diluted share, on revenue of \$1.72 billion for the same period in the prior year. For 2013, Mylan reported net income of \$623.7 million, or \$1.58 per diluted share, on revenue of \$6.91 billion, compared to net income of \$640.9 million, or \$1.52 per diluted share, on revenue of \$6.80 billion for 2012.

444. In the February 27, 2014 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net revenues of \$176.1 million, an increase of \$20.2 million, or 13.0%, from the comparable prior year period of \$155.9 million. The most significant contributor to Specialty segment revenues continues to be the EpiPen® Auto-Injector, sales . . . of which increased as a result of favorable pricing and volume. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector.

Gross profit for the three months ended December 31, 2013 was \$796.0 million, and gross margins were 44%. For the three months ended December 31, 2012, gross profit was \$742.3 million, and gross margins were 43%. Adjusted gross profit, as further defined below, for the three months ended December 31, 2013 was \$930.2 million and adjusted gross margins were 51% as compared to adjusted gross profit of \$845.4 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were favorably impacted in the current quarter as a result of higher margins on new product introductions and favorable pricing and volume on the EpiPen® Auto-Injector. These increases were partially offset by lower gross margins on existing products primarily as a result of unfavorable pricing within the Generics segment as discussed above.

445. The statements in ¶¶443-444 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan

had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

446. In its February 27, 2014 Annual Report on Form 10-K, Mylan stated, in part:

*Specialty Segment*

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. Mylan Specialty's portfolio consists of primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EpiPen® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

\* \* \*

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from***

*15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.* We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

447. The statements in ¶446 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

448. In the February 27, 2014 10-K, Mylan stated, in part:

### **Competition**

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:

*United States.* The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio offering size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the



treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

449. The statements in ¶448 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by engaging in anticompetitive conduct to eliminate competitors of the EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and pharmacy benefits managers contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anticompetitive conduct "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel in which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

450. In the February 27, 2014 10-K, Mylan stated, in part:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these



calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

\* \* \*

Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, *should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken*, and may impose civil and/or criminal sanctions.

451. The statements in ¶450 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its reporting and payment obligations under Medicaid; (2) classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan’s classification of the EpiPen was not subject to a “risk of error[],” as that risk of error had already materialized; (4) Mylan’s classification of the EpiPen was not subject to “differing interpretations,” as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; and (5) a government authority had already taken a position “with regard to how to properly calculate . . . payments” that was “contrary to a position [Mylan had] taken,” as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination.

452. On May 1, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2014 (the “May 1, 2014 8-K”). For the quarter, Mylan reported net income of

\$115.9 million, or \$0.29 per diluted share, on revenue of \$1.72 billion, compared to net income of \$106.9 million, or \$0.27 per diluted share, on revenue of \$1.63 billion for the same period in the prior year. In the May 1, 2014 8-K, Mylan stated, in relevant part:

For the three months ended March 31, 2014, Mylan's Specialty segment reported third party net sales of \$194.7 million, a decrease of \$16.9 million, or 8.0%, from the comparable prior year period of \$211.6 million. The decrease was the result of lower sales of the EpiPen® Auto-Injector, as a result of lower volumes due to a decline in wholesaler inventory levels during the quarter, only partially offset by favorable pricing. Third party net sales in the Specialty segment were also negatively impacted in the current period as a result of the discontinuation of a contract manufacturing agreement unrelated to the EpiPen® Auto-Injector. Offsetting these declines, sales of the Perforomist® Inhalation Solution increased from the comparable prior year period as a result of favorable pricing and volume.

Gross profit for the three months ended March 31, 2014, was \$737.8 million and gross margins were 43.0%. For the three months ended March 31, 2013, gross profit was \$693.5 million, and gross margins were 42.5%. Adjusted gross profit, as further defined below, for the three months ended March 31, 2014 was \$865.6 million and adjusted gross margins were 50% as compared to adjusted gross profit of \$796.5 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were positively impacted in the current year as a result of higher margins on new products. These increases were partially offset by unfavorable pricing on existing products, including products launched in the prior year.

453. The statements in ¶452 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

454. On August 7, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended June 30, 2014 (the "August 7, 2014 8-K"). For the quarter, Mylan reported net

income of \$125.2 million, or \$0.32 per diluted share, on revenue of \$1.84 billion, compared to net income of \$177.7 million, or \$0.46 per diluted share, on revenue of \$1.70 billion for the same period in the prior year. In the August 7, 2014 8-K, Mylan stated, in relevant part:

### **Specialty Segment Revenue**

**Specialty segment** reported third party net sales of \$287.8 million for the quarter, an increase of 22% when compared to the prior year period. The increase was due to higher sales of the **EpiPen® Auto-Injector** driven by market expansion, as well as price. The effect of constant currency on Specialty segment third party net sales was insignificant. The EpiPen® Auto-Injector remains on track to become a billion dollar product in 2014.

### **Total Gross Profit**

**Adjusted gross profit** was \$923.4 million and **adjusted gross margins** were 50% as compared to adjusted gross profit of \$834.2 million and adjusted gross margins of 49% in the comparable prior year period. Strong adjusted gross margins were the result of growth in the EpiPen® Auto-Injector combined with the benefits and efficiencies of Mylan's vertically integrated operating platform. These increases were offset partially by unfavorable pricing on existing products, including products launched in the prior year. **GAAP gross profit** for the quarter was \$808.8 million and **GAAP gross margins** were 44% as compared to GAAP gross profit of \$742.4 million and GAAP gross margins of 44% in the comparable prior year period.

### **Total Profitability**

**Adjusted earnings from operations** for the quarter were \$409.9 million, down less than 1% from the comparable prior year period. The decrease in adjusted earnings from operations was due to an increase in **SG&A** and **R&D**. The increase in SG&A was impacted by our direct-to-consumer marketing campaign for the EpiPen® Auto-Injector, and to a lesser extent, by increases in legal and marketing costs in the North American region of the Generics business to support anticipated new product launches. R&D was at the high end of the guidance range as we continued to progress our biologics and respiratory growth platforms. **GAAP earnings from operations** were \$226.1 million for the quarter, a decrease of 27% from the comparable prior year period.

455. The statements in ¶454 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive

conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

456. On October 30, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended September 30, 2014 (the "October 30, 2014 8-K"). For the quarter, Mylan reported net income of \$499.1 million, or \$1.26 per diluted share, on revenue of \$2.08 billion, compared to net income of \$158.9 million, or \$0.40 per diluted share, on revenue of \$1.76 billion for the same period in the prior year. In the October 30, 2014 8-K, Mylan stated, in part:

#### **Specialty Segment Revenue**

**Specialty segment** reported third party net sales of \$462.0 million for the quarter, an increase of 29% when compared to the prior year period. The increase was due to higher net sales of the **EpiPen® Auto-Injector** driven by increased volume and favorable pricing. The increased quarterly volume resulted from double-digit growth of the epinephrine auto-injector market. The EpiPen® Auto-Injector remains on track to become a billion dollar product in 2014.

#### **Total Gross Profit**

**Adjusted gross profit** was \$1.13 billion and **adjusted gross margins** were 54% for the quarter as compared to adjusted gross profit of \$903.2 million and adjusted gross margins of 51% in the comparable prior year period. Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector. **GAAP gross profit** for the quarter was \$1.01 billion and **GAAP gross margins** were 49% as compared to GAAP gross profit of \$808.5 million and GAAP gross margins of 46% in the comparable prior year period.

#### **Total Profitability**

**Adjusted earnings from operations** for the quarter were \$659.3 million, up 43% from the comparable prior year period. **SG&A expense** increased from the prior year period as a result of increased selling and marketing investments related to the EpiPen® Auto-Injector franchise as well as increased legal and marketing costs in the North American region to support anticipated new product launches. **R&D expense** also increased as we continued to invest in our biologics and respiratory growth platforms. **GAAP earnings from operations** were \$495.0 million for the quarter, an increase of 46% from the comparable prior year period.

457. The statements in ¶456 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

#### **D. Defendants' False and Misleading Statements in 2015**

458. On March 2, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "March 2, 2015 8-K"). For the quarter, Mylan reported net income of \$189.2 million, or \$0.47 per diluted share, on revenue of \$2.08 billion, compared to net income of \$180.2 million, or \$0.45 per diluted share, on revenue of \$1.81 billion for the same period in the prior year. For 2014, Mylan reported net income of \$929.4 million, or \$2.34 per diluted share, on revenue of \$7.72 billion, compared to net income of \$623.7 million, or \$1.58 per diluted share, on revenue of \$6.91 billion for 2013. In the March 2, 2015 8-K, Mylan stated, in part:

##### ***Specialty Segment Revenue***

**Specialty segment** reported third party net sales of \$242.7 million for the quarter, an increase of 38% when compared to the prior year period. The increase was due to higher net sales of the **EpiPen® Auto-Injector** driven by increased volume and favorable pricing. The increased quarterly volume resulted from continued growth of the epinephrine auto-injector market. Importantly, the EpiPen® Auto-Injector became Mylan's first product to reach \$1 billion in annual net sales in 2014.

##### ***Total Gross Profit***

**Adjusted gross profit** was \$1.12 billion and **adjusted gross margins** were 54% for the quarter as compared to adjusted gross profit of \$930.2 million and adjusted gross margins of 51% in the comparable prior year period. Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector. **GAAP gross profit** for the quarter was \$969.0 million and **GAAP gross margins** were 47% as compared to GAAP gross profit of \$795.9 million and GAAP gross margins of 44% in the comparable prior year period.

### ***Total Profitability***

**Adjusted earnings from operations** for the quarter were \$606.0 million, up 34% from the comparable prior year period. **SG&A expense** increased from the prior year period as a result of increased selling and marketing investments related to the EpiPen® Auto-Injector franchise as well as increased infrastructure costs. **R&D expense** also increased as we continued to invest in our biologics and respiratory growth platforms. **GAAP earnings from operations** were \$392.5 million for the quarter, an increase of 44% from the comparable prior year period.

459. The statements in ¶458 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

460. In its March 2, 2015 Annual Report on Form 10-K, Mylan stated, in part:

### ***Specialty Segment***

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector. During 2014, the EpiPen® Auto-Injector became the first Mylan product to reach \$1 billion in annual net sales.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned

subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the “Guidelines for the Diagnosis and Management of Food Allergy in the United States.” These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

\* \* \*

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the “PPACA”) and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages effective January 1, 2010. ***The required rebate is currently 13% of the average manufacturer’s price for sales of Medicaid-reimbursed non-innovator products, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed innovator or single-source products require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer’s price or the difference between the average manufacturer’s price and the best price during a specific period.*** We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

461. The statements in ¶460 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer’s price for sales of Medicaid-reimbursed products.

462. In the March 2, 2015 10-K, Mylan stated, in part:

### **Competition**

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:



*United States.* The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

463. The statements in ¶462 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by engaging in anticompetitive conduct to eliminate competitors of the EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and pharmacy benefits managers contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anticompetitive conduct "the U.S. pharmaceutical marketplace



[was] highly sensitive to price,” the price-fixing cartel in which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

464. In the March 2, 2015 10-K, Mylan stated, in part:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company’s participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

\* \* \*

Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, *should there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken*, and may impose civil and/or criminal sanctions.

465. The statements in ¶464 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its reporting and payment obligations under Medicaid; (2) the classification of the EpiPen was not complex and did not involve subjective

decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error[]," as that risk of error had already materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority had already taken a position "with regard to how to properly calculate . . . payments" that was "contrary to a position [Mylan had] taken," as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" with regard to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an unrealized risk – the risk had already materialized because Mylan was already under investigation by the DOJ.

466. On May 5, 2015, Mylan held a conference call with investors during which Malik made the following statements:

Mylan delivered solid first-quarter results, kicking off what we believe will be yet another year of strong financial performance for the Company.

Sales during the quarter totaled nearly \$1.9 billion and constant currency and fees of 15% compared to the same period last year. Adjusted diluted EPS came in at \$0.70, an increase of 6% compared with the first quarter of 2014.

As highlighted on this slide, *all of our regions within the generic segment experienced strong constant currency revenue growth which was a result of new product introductions.*

467. The statements in ¶466 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including

through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

468. On May 5, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended March 31, 2015 (the "May 5, 2015 8-K"). For the quarter, Mylan reported net income of \$56.6 million, or \$0.13 per diluted share, on revenue of \$1.87 billion, compared to net income of \$115.9 million, or \$0.29 per diluted share, on revenue of \$1.72 billion for the same period in the prior year. In the May 5, 2015 8-K, Mylan stated, in relevant part:

***Specialty Segment Revenue***

**Specialty segment** reported third party net sales of \$211.1 million for the quarter, an increase of 8% when compared to the prior year period. This increase was primarily due to higher net sales of the **EpiPen® Auto-Injector** driven by increased volume.

***Total Gross Profit***

**Adjusted gross profit** was \$990.6 million and **adjusted gross margins** were 53% for the quarter as compared to adjusted gross profit of \$865.6 million and adjusted gross margins of 50% in the comparable prior year period. The current quarter increase was due to new product introductions and net sales from acquisition. **GAAP gross profit** for the quarter was \$830.1 million and **GAAP gross margins** were 44% as compared to GAAP gross profit of \$737.8 million and GAAP gross margins of 43% in the comparable prior year period.

***Total Profitability***

**Adjusted earnings from operations** for the quarter were \$429.7 million, up 9% from the comparable prior year period. **R&D expense** increased primarily from the continued investment in our biologics and respiratory growth programs. **SG&A expense** increased from the prior year period as a result of increased costs related to acquired businesses and increased selling and marketing costs, primarily stemming from the EpiPen® Auto-Injector direct-to-consumer marketing campaign. **GAAP earnings from operations** were \$159.3 million for the quarter, a decrease of 33% from the comparable prior year period. This decrease in earnings from operations during the current quarter was primarily the result of increased acquisition related costs and increased amortization expense as a result of the acquisition of the EPD Business.

469. The statements in ¶468 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

470. In its May 8, 2015 Quarterly Report on Form 10-Q, Mylan made the following statements:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

\* \* \*

Any governmental agencies or authorities that have commenced, or may commence, an investigation of us relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report

payments – and even in the absence of any such ambiguity – a governmental authority may take a position contrary to a position we have taken, and may impose or pursue civil and/or criminal sanctions.

471. The statements in ¶470 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its reporting and payment obligations under Medicaid; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan’s classification of the EpiPen was not subject to a “risk of error[,]” as that risk of error had already materialized; (4) Mylan’s classification of the EpiPen was not subject to “differing interpretations,” as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority had already taken a position “with regard to how to properly calculate . . . payments” that was “contrary to a position [Mylan had] taken,” as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan “could [be] subject[ed] to investigation” with regard to its “reporting and payment obligations related to . . . Medicaid” was no longer merely an unrealized risk – the risk had already materialized because Mylan was already under investigation by the DOJ.

472. On August 6, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company’s financial and operating results for the quarter ended June 30, 2015 (the “August 6, 2015 8-K”). For the quarter, Mylan reported net income of \$167.8 million, or \$0.32 per diluted share, on revenue of \$2.37 billion, compared to net income of \$125.2 million, or \$0.32 per diluted share, on revenue of \$1.84 billion for the same period in the prior year. In the August 6, 2015 8-K, Mylan stated, in part:

***Specialty Segment Revenue***

**Specialty segment** reported third party net sales of \$301.9 million for the quarter, an increase of 5% when compared to the prior year period. This increase was primarily due to growth across the segment, including higher volumes of the **EpiPen® Auto-Injector**.

***Total Gross Profit***

**Adjusted gross profit** was \$1.28 billion and **adjusted gross margins** were 54% for the quarter as compared to adjusted gross profit of \$923.4 million and adjusted gross margins of 50% in the comparable prior year period. The current quarter increase was primarily due to net sales from the acquisition of the EPD Business and net sales from new products. **GAAP gross profit** for the quarter was \$1.01 billion and **GAAP gross margins** were 43% as compared to GAAP gross profit of \$808.8 million and GAAP gross margins of 44% in the comparable prior year period.

473. The statements in ¶472 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

474. On August 6, 2015, Mylan held a conference call with investors during which CFO Sheehan cited "increased margins on existing [generic] products in North America" and noted "positive pricing in North America," even as Mylan experienced "mid-single-digit price declines in Europe . . . [a]nd low-single-digit price in the rest of world."

475. The statements in ¶474 were misleading because they failed to disclose that Mylan's margins on generic drugs had resulted in significant part from Mylan's anticompetitive activity, including allocation of the market for, and fixing the prices of, generic drugs.

476. On the August 6, 2015 conference call, Malik made the following statements:

[A]ll of our regions and businesses contributed to the outstanding performance we delivered during the second quarter, with each of the regions delivering very impressive double-digit growth. Our Global Generics segment generated third-party net sales of just over \$2 billion, an increase year over year of 43% on a constant currency basis. In North America, sales totaled \$937 million, up 27% year over year. Our legacy business grew by 22%. ***This impressive growth is attributed to continued strong performance of sales from new products as less stable pricing and higher volumes on existing products.***

477. The statements in ¶476 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

478. On October 30, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended September 30, 2015 (the "October 30, 2015 8-K"). For the quarter, Mylan reported net income of \$428.6 million, or \$0.83 per diluted share, on revenue of \$2.71 billion, compared to net income of \$499.1 million, or \$1.26 per diluted share, on revenue of \$2.08 billion for the same period in the prior year. In the October 30, 2015 8-K, Mylan stated, in part:

***Specialty Segment Revenues***

**Specialty segment** reported third party net sales of \$437.8 million for the quarter, a decrease of 5% when compared to the prior year period. This decrease was primarily due to a lower average net selling price for the **EpiPen® Auto-Injector** as a result of competitive market conditions.



***Total Gross Profit***

**Adjusted gross profit** was \$1.58 billion and **adjusted gross margins** were 58% for the quarter as compared to adjusted gross profit of \$1.13 billion and adjusted gross margins of 54% in the comparable prior year period. The current quarter increase was primarily due to net sales from the acquired EPD Business, new product introductions and increased margins on existing products in North America. **GAAP gross profit** was \$1.32 billion and \$1.01 billion for the third quarter of 2015 and 2014, respectively. **GAAP gross margins** were 49% in both periods.

479. The statements in ¶478 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

480. On October 30, 2015, Mylan held a conference call with investors during which Malik made the following statements:

[A]ll of our divisions contributed to the outstanding performance we delivered during the third quarter with each delivering very impressive double digit revenue growth. Our global generic segment generated third party net sales of more than \$2.3 billion, a year on year increase of 48% on a constant currency basis.

In North America, sales were approximately \$1.1 billion, up 29% year-over-year on a constant currency basis. Our legacy business grew by 24% as a result of continued strong performance of sales from new products and high volumes on existing products offset by lower net pricing.

481. The statements in ¶480 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including



through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

**E. Defendants' False and Misleading Statements in 2016**

482. On February 10, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "February 10, 2016 8-K"). For the quarter, Mylan reported net income of \$194.6 million, or \$0.38 per diluted share, on revenue of \$2.49 billion, compared to net income of \$189.2 million, or \$0.47 per diluted share, on revenue of \$2.08 billion for the same period in the prior year. For 2015, Mylan reported net income of \$847.6 million, or \$1.70 per diluted share, on revenue of \$9.45 billion, compared to net income of \$929.4 million, or \$2.34 per diluted share, on revenue of \$7.72 billion for 2014.

483. In the February 10, 2016 8-K, Mylan stated, in part:

***Specialty Segment Revenues***

**Specialty segment** reported third party net sales were \$254.1 million for the quarter, an increase of 5% when compared to the prior year period. This increase was primarily due to higher net sales of the **EpiPen® Auto-Injector** due to higher volumes, but with the same net payor pricing dynamics that existed throughout 2015.

***Total Gross Profit***

**Adjusted gross profit** was \$1.40 billion and **adjusted gross margins** were 56% for the quarter as compared to adjusted gross profit of \$1.12 billion and adjusted gross margins of 54% in the comparable prior year period. The current quarter increase was primarily due to net sales from the acquired EPD Business and new product introductions, partially offset by pricing reductions. **GAAP gross profit** was \$1.06 billion and \$969.0 million for the fourth quarter of 2015 and 2014, respectively. **GAAP gross margins** were 43% and 47% in the fourth quarter of 2015 and 2014, respectively.

\* \* \*

**Specialty segment** reported third party net sales of \$1.20 billion for the year, an increase of 1% when compared to the prior year. This increase was partially due to higher volumes of the **EpiPen® Auto-Injector**, which was offset by lower

pricing. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row. In addition, sales of the Perforomist® Inhalation Solution and ULTIVA® increased by double digit percentage points from the prior year.

484. The statements in ¶¶482-483 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

485. In its February 16, 2016 Annual Report on Form 10-K, Mylan stated, in relevant part:

**Competition**

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Competitive factors in the major markets in which we participate can be summarized as follows:

*North America*

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as branded companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a branded manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

486. The statements in ¶485 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by engaging in anticompetitive conduct to eliminate competitors of the EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and pharmacy benefits managers contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anticompetitive conduct "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel in which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

487. In the February 16, 2016 10-K, Mylan stated, in relevant part:

***Specialty Segment***

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. For the year ended December 31, 2015, Specialty third party net sales were \$1.20 billion. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through

the sale of the EpiPen® Auto-Injector. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the “Guidelines for the Diagnosis and Management of Food Allergy in the United States.” These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® Auto-Injector brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

\* \* \*

Medicaid, a U.S. federal healthcare program, requires pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. *Sales of Medicaid-reimbursed non-innovator products require manufacturers to rebate 13% of the average manufacturer’s price and, effective 2017, adjusted by the Consumer Price Index-Urban (the “CPI-U”) based on certain data. Sales of the Medicaid-reimbursed innovator or single-source products require manufactures to the rebate the greater of approximately 23% of the average manufacturer’s price or the difference between the average manufacturer’s price and the best price adjusted by the CPI-U based on certain data.* We believe that federal or state governments will continue to enact measures aimed at reducing the cost of drugs to the public.

488. The statements in ¶487 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer’s price for sales of Medicaid-reimbursed products.

489. In the February 16, 2016 10-K, Mylan stated:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTHCARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT

OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal healthcare programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable government agencies . . .

\* \* \*

[S]hould there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of any such ambiguity – a government authority may take a position contrary to a position we have taken . . .

490. The statements in ¶489 were misleading because they failed to disclose that:

(1) Mylan had in fact already failed to comply with its reporting and payment obligations under Medicaid; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error[]," as that risk of error had already materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority had already taken a position "with regard to how to properly calculate payments" that was "contrary to a position [Mylan had] taken," as the HHS IG and CMS had already determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" with regard to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an

unrealized risk – the risk had already materialized because Mylan was already under investigation by the DOJ.

491. On May 3, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended March 31, 2016 (the "May 3, 2016 8-K"). For the quarter, Mylan reported net income of \$13.9 million, or \$0.03 per diluted share, on revenue of \$2.19 billion, compared to net income of \$56.6 million, or \$0.13 per diluted share, on revenue of \$1.87 billion for the same period in the prior year. In the May 3, 2016 8-K, Mylan stated, in relevant part:

***Specialty Segment Revenues***

**Specialty segment** reported third party net sales were \$247.9 million for the quarter, an increase of 17% when compared to the prior year period. This increase was primarily the result of higher volumes of the **EpiPen® Auto-Injector** and higher sales of the **Perforomist® Inhalation Solution**.

***Total Gross Profit***

**Adjusted gross profit** was \$1.18 billion and **adjusted gross margins** were 54% for the quarter as compared to adjusted gross profit of \$990.6 million and adjusted gross margins of 53% in the comparable prior year period. The current quarter increase was primarily due to the incremental contribution from established products in the first quarter of 2016 as well as new product introductions, partially offset by decreased margins on existing products in North America. **U.S. GAAP gross profit** was \$907.0 million and \$830.1 million for the first quarter of 2016 and 2015, respectively.

492. The statements in ¶491 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

493. On May 3, 2016, Mylan held a conference call with investors during which Malik made the following statements:

[O]ur business continues to perform strongly across all areas, reflecting the powerful global manufacturing, R&D, and commercial infrastructure we have in place. And the opportunities we are seeing to leverage our expansive product portfolio across our geographies and channels as one Mylan.

In our North America generics business sales totaled \$920 million, a year-over-year increase of 8%. *Growth came primarily from sales of new products and to a lesser extent from incremental sales of established products, while the pricing environment was consistent with our expectations and guidance to you.*

494. The statements in ¶493 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

495. On August 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended June 30, 2016 (the "August 9, 2016 8-K"). For the quarter, Mylan reported net income of \$168.4 million, or \$0.33 per diluted share, on revenue of \$2.56 billion, compared to net income of \$167.8 million, or \$0.32 per diluted share, on revenue of \$2.37 billion for the same period in the prior year.

496. In the August 9, 2016 8-K, Mylan stated, in relevant part:

**Specialty segment** third party net sales were \$402.5 million for the quarter, an increase of 33% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the **EpiPen®**



**Auto-Injector**, and higher sales of the **Perforomist® Inhalation Solution** and **ULTIVA®**.

\* \* \*

**Specialty segment** third party net sales were \$650.4 million for the six months ended June 30, 2016, an increase of 27% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the **Perforomist® Inhalation Solution** and **ULTIVA®**.

***Total Gross Profit***

Gross profit was \$2.08 billion and \$1.84 billion for the six months ended June 30, 2016 and 2015, respectively. Gross margins were 44% and 43% for the six months ended June 30, 2016 and 2015, respectively. Gross margins were positively impacted primarily by new product introductions and favorable Specialty sales, partially offset by higher amortization expense due to acquisitions completed in 2015. Adjusted gross profit was \$2.63 billion and adjusted gross margins were 55% for the six months ended June 30, 2016 compared to adjusted gross profit of \$2.27 billion and adjusted gross margins of 54% in the prior year period. Adjusted gross margins were positively impacted primarily by new product introductions and favorable Specialty sales in the first half of 2016.

497. The statements in ¶¶495-496 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

498. On August 9, 2016, Mylan held a conference call with investors during which Malik made the following statements:

We continue to see solid performance across our businesses during the second quarter, once again demonstrating that the scale and diversity we have created provides us with the strength, consistency, and resilience to ever-evolving market conditions, further differentiating us from our competitors. . . .



Overall, our generics business delivered third-party net sales of approximately \$2.1 billion for the quarter, an increase of 4% compared to prior-year quarter. In North America, our generics business grew approximately 6% to just over \$1 billion. ***Growth came primarily from a significant number of new product introductions, leveraging our strong global platform.***

We launched 18 new products during this quarter. ***The generic pricing environment was again consistent with our expectations and guidance to you.***

499. The statements in ¶498 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

500. On November 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended September 30, 2016 (the "November 9, 2016 8-K"). For the quarter, Mylan reported a net loss of \$119.8 million, or a loss per share of \$0.23, on revenue of \$3.06 billion.

501. In the November 9, 2016 8-K, Mylan stated, in relevant part:

**Specialty segment** third party net sales were \$418.7 million for the quarter, a decrease of 4% when compared to the prior year period. This decrease was primarily the result of lower unit volumes due to the timing of wholesaler purchases of the **EpiPen® Auto-Injector** in anticipation of the authorized generic launch.

***Total Gross Profit***

**Gross profit** was \$1.28 billion and \$1.32 billion for the third quarter of 2016 and 2015, respectively. Gross margins were 42% and 49% in the third quarter of 2016 and 2015, respectively. Gross margins were negatively impacted in the current quarter by higher purchase accounting related items, primarily amortization, as a result of the acquisition of Meda and the Topicals Business, and the significant contribution in the prior year period of new products. Adjusted gross profit was \$1.74 billion and adjusted gross margins were 57% for the quarter compared to

adjusted gross profit of \$1.58 billion and adjusted gross margins of 58% in the prior year period. Adjusted gross margins were positively impacted by the acquisition of Meda and new products, offset by the significant contribution in the prior year period of new products.

\* \* \*

**Specialty segment** third party net sales were \$1.07 billion for the nine months ended September 30, 2016, an increase of 12% when compared to the prior year period. This increase was primarily the result of the realization of the benefits of customer contract negotiations over the last several quarters related to the **EpiPen® Auto-Injector**, and higher sales of the **Perforomist® Inhalation Solution** and **ULTIVA®**, partially offset by lower volumes across the segment.

502. The statements in ¶¶500-501 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

503. On November 9, 2016, Mylan held a conference call with investors during which Malik made the following statements:

Overall, our generics business delivered third-party net sales of approximately \$2.6 billion for the quarter, an increase of 17% compared to the prior year quarter. Meda contributed \$324 million of these revenues, in-line with our expectations.

In North America, our generics business grew approximately 1% to just about \$1.1 billion on a constant-currency basis. ***Growth came primarily from our acquisitions of both Meda and the Renaissance topicals business as well as new product introductions.*** Note that we have a challenging year-over-year comparison this quarter due to significant contribution from the new products in the last year's third quarter, especially esomeprazole, lidocaine and bexarotene. We also experienced increased competition with new entrants on a number of other key products.

*The generic pricing environment was again consistent with our expectations and previous guidance.*

504. The statements in ¶503 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan had knowingly misclassified the EpiPen for the purposes of the MDRP and, accordingly, had overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of the EpiPen from the market and allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

#### **F. Defendants' False and Misleading Statements in 2017**

505. On March 1, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2016 (the "March 1, 2017 8-K"). For the quarter, Mylan reported net income of \$417.5 million, or \$0.78 per diluted share, on revenue of \$3.27 billion. For 2016, Mylan reported net earnings of \$480 million, or \$0.92 per diluted share, on revenue of \$11.08 billion.

506. In the March 1, 2017 8-K, Mylan stated, in part:

- Third party net sales from **North America** were \$1.57 billion for the quarter, an increase of 22% when compared to the prior year period. This increase was principally due to net sales from the acquisitions of Meda AB ("Meda") and the non-sterile, topicals-focused business of Renaissance Acquisition Holdings, LLC (the "Topicals business"), and to a lesser extent, net sales from new products. Partially offsetting this increase was lower pricing and volumes on existing products.

\* \* \*

Gross profit was \$1.34 billion and \$1.06 billion for the fourth quarter of 2016 and 2015, respectively. Gross margins were 41% and 43% in the fourth quarter of 2016 and 2015, respectively. Gross margins were negatively impacted in the current quarter due to increased amortization of intangible assets, the amortization of acquisition-related inventory fair value adjustments and intangible asset impairment

charges. This negative impact was partially offset by the positive impact of net sales from new products. Adjusted gross profit was \$1.85 billion and adjusted gross margins were 57% for the quarter compared to adjusted gross profit of \$1.40 billion and adjusted gross margins of 56% in the prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of net sales from new products and the net impact of acquisitions.

\* \* \*

- Third party net sales from **North America** were \$5.63 billion for the year ended December 31, 2016, an increase of 10% when compared to the prior year. The increase was principally due to net sales from the acquisitions of Meda, the Topicals Business and the incremental sales from the EPD Business, and to a lesser extent, net sales from new products. These increases were partially offset by lower volume and pricing on existing products. As anticipated, the U.S. generics products experienced price erosion in the mid-single digits. The unfavorable impact of foreign currency translation on current year third party net sales was approximately \$7 million, or less than 1% within North America.

\* \* \*

Gross profit was \$4.70 billion and \$4.22 billion for the year ended December 31, 2016 and 2015, respectively. Gross margins were 42% and 45% for the year ended December 31, 2016 and 2015, respectively. Gross margins were negatively impacted in the current year due to increased amortization of intangible assets and purchase accounting related items consistent with the fourth quarter. This negative impact was partially offset by the positive impact of net sales from new products. Adjusted gross profit was \$6.21 billion and \$5.25 billion for the year ended December 31, 2016 and 2015, respectively. Adjusted gross margins were 56% in both 2016 and 2015. Adjusted gross margins were positively impacted in the current year as a result of net sales from new products and the net impact of acquisitions.

507. The statements in ¶¶505-506 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

508. In its March 1, 2017 Annual Report on Form 10-K, Mylan stated, in relevant part:

## Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Our OTC products face competition from other major pharmaceutical companies and retailers who carry their own private label brands. Our ability to compete in the various OTC markets is affected by several factors, including customer acceptance, reputation, product quality, pricing and the effectiveness of our promotional activities. OTC markets are highly fragmented in terms of product categories and geographic market coverage.

Competitive factors in the major markets in which we participate can be summarized as follows:

### *North America*

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.

509. The statements in ¶508 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (3) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (4) while absent anticompetitive conduct “the U.S. pharmaceutical marketplace [was] highly sensitive to price,” the price-fixing cartel in which Mylan was a participant controlled the prices of generic drugs

for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

510. On May 10, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended March 31, 2017 (the "May 10, 2017 8-K"). For the quarter, Mylan reported net earnings of \$66.4 million, or \$0.12 per diluted share, on revenue of \$2.72 billion.

511. In the May 10, 2017 8-K, Mylan stated, in relevant part:

Gross profit was \$1.09 billion and \$907.0 million for the first quarter of 2017 and 2016, respectively. Gross margins were 40% and 41% in the first quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in the current quarter due to increased amortization expense as a result of the acquisitions of Meda and the Topicals Business, lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by the contributions from the acquired businesses noted above. Adjusted gross profit was \$1.45 billion and adjusted gross margins were 53% for the first quarter of 2017 compared to adjusted gross profit of \$1.18 billion and adjusted gross margins of 54% in the prior year period. Adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by the contributions from the acquired businesses.

512. The statements in ¶¶510-511 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

513. On August 9, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended June 30, 2017 (the "August 9, 2017 8-K"). For the quarter, Mylan reported net earnings of \$297.0 million, or \$0.55 per diluted share, on revenue of \$2.96 billion.

514. In the August 9, 2017 8-K, Mylan stated, in relevant part:

Gross profit was \$1.23 billion and \$1.17 billion for the second quarter of 2017 and 2016, respectively. Gross margins were 41% and 46% in the second quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in the current quarter by increased amortization expense as a result of the acquisitions of Meda and the Topicals Business by approximately 335 basis points and lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 320 basis points, partially offset by the contributions from the acquired businesses. Adjusted gross profit was \$1.60 billion and adjusted gross margins were 54% for the second quarter of 2017 compared to adjusted gross profit of \$1.45 billion and adjusted gross margins of 56% in the prior year period. Adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 260 basis points, partially offset by the contributions from acquired businesses.

515. The statements in ¶¶513-514 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

#### **G. Defendants' False and Misleading Statements in 2018**

516. On February 28, 2018, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2017 (the "February 28, 2018 8-K"). For the year, Mylan reported revenue of \$11.91 billion, and for the quarter, Mylan reported revenue of \$3.24 billion.

517. In the February 28, 2018 8-K, Mylan stated, in relevant part:

"In 2017, we delivered an 8% increase in total revenues year over year, as strong performances by our Europe and Rest of World segments more than offset ongoing volatility across the healthcare industry in the U.S. marketplace."

\* \* \*

**Gross profit** was \$1.29 billion and \$1.34 billion for the fourth quarter of 2017 and 2016, respectively. Gross margins were 40% and 41% in the fourth quarter of 2017 and 2016, respectively. **Adjusted gross profit** was \$1.80 billion and adjusted gross margins were 55% for the fourth quarter of 2017 compared to adjusted



gross profit of \$1.85 billion and adjusted gross margins of 57% in the prior year period. Gross margins and adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by contributions from new products.

518. The statements in ¶¶516-517 were misleading because they failed to disclose that Mylan's net income, revenue, and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs (including through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

519. In its March 1, 2018 Annual Report on Form 10-K, Mylan stated, in relevant part:

**Competition**

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Our OTC products face competition from other major pharmaceutical companies and retailers who carry their own private label brands. Our ability to compete in the various OTC markets is affected by several factors, including customer acceptance, reputation, product quality, pricing and the effectiveness of our promotional activities. OTC markets are highly fragmented in terms of product categories and geographic market coverage.

Competitive factors in the major markets in which we participate can be summarized as follows:

*North America*

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name, OTC and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.



520. The statements in ¶519 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (3) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (4) while absent anticompetitive conduct “the U.S. pharmaceutical marketplace [was] highly sensitive to price,” the price-fixing cartel in which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

521. On May 9, 2018, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2018 (the “May 9, 2018 8-K”). For the quarter, Mylan reported revenue of \$2.68 billion.

522. In the May 9, 2018 8-K, Mylan stated, in relevant part:

Net sales from existing products on a constant currency basis decreased \$286.2 million primarily as a result of lower volumes, and to a lesser extent, pricing, which were partially offset by new product introductions of \$102.6 million. Sales were also negatively impacted by the adoption of new accounting standards of a net impact of approximately \$17.7 million. Mylan’s total revenues were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan’s subsidiaries in the European Union, India, the United Kingdom, Japan, and Australia.

523. The statements in ¶¶521-522 were misleading because they failed to disclose that Mylan’s financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs (including

through price-fixing activity in which Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

524. On August 8, 2018, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the quarter ended June 30, 2018 (the "August 8, 2018 8-K"). For the quarter, Mylan reported revenue of \$2.81 billion.

525. In the August 8, 2018 8-K, Mylan stated, in relevant part:

**Total revenues** were \$2.81 billion . . . .

The decrease in total revenues included lower net sales in the North America segment of 22%. This decrease was partially offset by net sales increases in the Europe segment of 4%, and in the Rest of World segment of 10%. The overall decrease in total revenues was primarily driven by a decrease in net sales from existing products. Net sales from existing products, partially offset by new product launches, decreased on a constant currency basis by approximately \$222.0 million primarily as a result of lower volumes, and to a lesser extent, pricing. . . . Mylan's total revenues were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in the European Union, which was partially offset by the unfavorable impact from changes in the Indian Rupee.

526. The statements in ¶¶524-525 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

#### **H. Defendants' False and Misleading Statements in 2019**

527. On February 26, 2019, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC announcing certain of the Company's financial and operating results for the fourth quarter and year ended December 31, 2018 (the "February 26, 2019 8-K").

528. In the February 26, 2019 8-K, Mylan stated, in relevant part:

**U.S. GAAP gross profit** for the three months ended December 31, 2018 was \$1.02 billion and U.S. GAAP gross margins were 33%. For the three months ended December 31, 2017, U.S. GAAP gross profit was \$1.29 billion and U.S. GAAP gross margins were 40%. U.S. GAAP gross margins were negatively impacted by approximately 270 basis points related to the incremental amortization from product acquisitions and intangible asset impairment charges and by approximately 240 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the current quarter principally as a result of the activities at the Company's Morgantown plant. U.S. GAAP gross margins were also negatively impacted as a result of lower gross profit from the sales of existing products partially offset by gross margins on new product introductions primarily in North America. **Adjusted gross profit** was \$1.68 billion and adjusted gross margins were 55% for the three months ended December 31, 2018 compared to adjusted gross profit of \$1.80 billion and adjusted gross margins of 55% in the prior year period. Adjusted gross margins were negatively impacted by lower gross profit from sales of existing products partially offset by gross margins on new product introductions primarily in North America.

529. The statements in ¶528 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

530. In its February 27, 2019 Annual Report on Form 10-K, Mylan stated, in relevant part:

*We face vigorous competition that threatens the commercial acceptance and pricing of our products.*

The pharmaceutical industry is highly competitive. We face competition from other pharmaceutical manufacturers globally, some of whom are significantly larger than we are. Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including but not limited to the possibility that they may have:

- proprietary processes or delivery systems;
- larger or more productive R&D and marketing staff;
- larger or more efficient production capabilities in a particular therapeutic area;
- more experience in preclinical testing and human clinical trials;

- more products; or
- more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

We also face increasing competition from lower-cost generic products and other branded products. . . .

Competitors' products may also be safer, more effective, more effectively marketed or sold, or have lower prices or better performance features than ours. We cannot predict with certainty the timing or impact of competitors' products.

531. The statements in ¶530 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; and (3) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive.

532. On May 7, 2019, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and ended March 31, 2019 (the "May 7, 2019 8-K").

533. In the May 7, 2019 8-K, Mylan stated, in relevant part:

**U.S. GAAP gross profit** was \$805.2 million and \$984.3 million for the three months ended March 31, 2019 and 2018, respectively. **U.S. GAAP gross margins** were 32% and 37% for the three months ended March 31, 2019 and 2018, respectively. U.S. GAAP gross margins were negatively impacted by approximately 60 basis points related to the incremental amortization from product acquisitions. U.S. GAAP gross margins were also negatively affected by approximately 280 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the current period principally as a result of the activities at the Company's Morgantown plant. In addition, U.S. GAAP gross margins were negatively impacted as a result of lower gross profit for sales of existing products partially offset by the impact from new product sales, primarily in North America.

534. The statements in ¶533 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and fix the prices of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

### **VIII. LOSS CAUSATION**

535. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff.

536. Throughout the Relevant Period, the prices of the Company's securities were artificially inflated and/or maintained at artificially high levels as a result of defendants' materially false and misleading statements and omissions identified herein.

537. The prices of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged herein to have been concealed from the market, and/or the effects thereof, materialized and/or were revealed, causing Plaintiff's losses.

538. Mylan's failure to disclose the fraudulent activity artificially inflated the value of Mylan's shares and/or maintained those shares at an artificially high levels, and the revelation and/or materialization of this information and/or the risks concealed by Mylan's fraud resulted in substantial losses to Plaintiff.

**A. August 19-24, 2016**

539. On August 17, 2016, at 6:42 p.m. EST, *NBC News* published an article, titled “EpiPen Price Hike Has Parents of Kids with Allergies Scrambling Ahead of School Year,” highlighting the price increases in the EpiPen over the prior years.<sup>43</sup>

540. On August 19, 2016 at 6:13 p.m. EST, *NBC News* published an article, titled “Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers ‘Vultures,’” stating: “A growing chorus is calling on the Mylan pharmaceutical company to justify its price hikes on EpiPens.”<sup>44</sup>

541. On August 20, 2016, Senator Amy Klobuchar of Minnesota, the top Democrat on the Judiciary Committee’s antitrust subcommittee, publicly called for a hearing to investigate “the enormous increase in the price of EpiPens.”<sup>45</sup>

542. On August 22, 2016, Senator Charles Grassley of Iowa, Chairman of the Senate Judiciary Committee, sent a letter to CEO Bresch, which was published the same day. The letter stated that Senator Grassley was “concerned that the substantial price increase could limit access to a much-needed medication” and requested additional information on the price increases.<sup>46</sup> Also on

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<sup>43</sup> Ben Popken, *EpiPen Price Hike Has Parents of Kids With Allergies Scrambling Ahead of School Year*, NBC News (Aug. 17, 2016), <http://www.nbcnews.com/business/economy/epipen-price-hike-has-parents-kids-allergies-scrambling-ahead-school-n633071>.

<sup>44</sup> Ben Popken, *Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers ‘Vultures,’* NBC News (Aug. 19, 2016), <http://www.nbcnews.com/business/consumer/martin-shkreli-weighs-epipen-scandal-calls-drug-makers-vultures-n634451>.

<sup>45</sup> Amy Klobuchar, *Klobuchar Calls for Judiciary Hearing and Investigation Into at Least 400 Percent Increase of EpiPen Packs* (Aug. 20, 2016), <https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-judiciary-hearing-and-investigation-into-at-least-400-percent-increase-of-epipen-packs>.

<sup>46</sup> Letter from Charles E. Grassley, U.S. Senator, to Heather Bresch, CEO Mylan N.V. (Aug. 22, 2016), <https://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20%28EpiPen%29.pdf>.

August 22, 2016, Senator Klobuchar sent a letter to the FTC requesting an investigation into Mylan's price increase on the EpiPen.<sup>47</sup>

543. On August 24, 2016, *The New York Times* published an article, titled "Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic," in which it stated that the Company's history of pricing the product highlights a common tactic in the drug industry: sharply raising prices in the years just before a generic competitor reaches the market.<sup>48</sup>

544. On this news and other similar stories, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$6.17, or 12.5%, between August 19 and August 24, 2016 to close at \$43.15 on August 24, 2016.<sup>49</sup> Specifically, Mylan's share price fell \$0.66, or 1.34%, on August 19; \$0.76, or 1.56%, on August 22; \$2.28, or 4.76%, on August 23; and \$2.47, or 5.41%, on August 24, 2016.

## **B. September 2, 2016**

545. On September 2, 2016, *Inside Health Policy* published an article stating that CMS had "informed Mylan [that the Company] incorrectly classified EpiPen as a generic under the

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<sup>47</sup> Amy Klobuchar, *Klobuchar Calls for FTC Investigation of Mylan Pharmaceuticals for Possible Antitrust Violations in Light of Dramatic Price Increase of EpiPen Packs* (Aug. 22, 2016), <https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-ftc-investigation-of-mylan-pharmaceuticals-for-possible-antitrust-violations-in-light-of-dramatic-price-increase-of-epipen-packs>.

<sup>48</sup> Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, N.Y. Times (Aug. 24, 2016), [https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?\\_r=0](https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?_r=0).

<sup>49</sup> All quoted price drops in this complaint refer to drops in the share price of Mylan on the NASDAQ-GS.

Medicaid rebate program, which caused financial consequences for federal and state governments by reducing the amount of quarterly rebates Mylan owed for its product.”<sup>50</sup>

546. On this news, the risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price fell \$1.95, or 4.65%, to close at \$39.97 on September 2, 2016.

**C. October 5, 2016**

547. On October 5, 2016, *Bloomberg* reported that CMS had issued a letter stating that Mylan had for years overcharged Medicaid for the EpiPen, despite being told that the Company needed to provide larger discounts under the law. The CMS letter stated that from 2011 to 2015, the Medicaid health program spent approximately \$797 million on EpiPens, including rebates of roughly 13%, rather than the discount of 23.1% that Medicaid should have received. The letter stated that the government had previously “‘expressly told Mylan that the [EpiPen] product is incorrectly classified.’”<sup>51</sup>

548. On this news, the risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price fell \$1.19, or 3.13%, to close at \$36.84 on October 6, 2016.

**D. October 7, 2016**

549. On October 7, 2016, Evercore ISI released an analysis suggesting that Mylan may have overcharged Medicaid by over \$707 million on its purchases of EpiPens between 2011 and

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<sup>50</sup> Inside Health Policy, *CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates, Lawmakers Upset* (Sept. 2, 2016), <https://insidehealthpolicy.com/daily-news/cms-tells-mylan-it-incorrectly-classified-epipen-pay-lower-medicaid-rebates-lawmakers>.

<sup>51</sup> Robert Langreth, *Mylan Accused by U.S. of Overcharging Medicaid for EpiPen*, *Bloomberg News* (Oct. 5, 2016), <https://www.bloomberg.com/news/articles/2016-10-05/mylan-overcharged-u-s-on-epipen-for-years-u-s-says>.



2015.<sup>52</sup> On the same day, Mylan announced that it had agreed to pay \$465 million to settle the DOJ's investigation into Mylan's classification of the EpiPen for the purposes of the MDRP.<sup>53</sup>

550. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$0.90, or 2.44%, to close at \$35.94 on October 7, 2016.

#### **E. October 12, 2016**

551. On October 11, 2016, at 6:40 p.m. EST, *CNBC* reported that an Evercore ISI analyst had concluded that the alleged settlement agreement Mylan announced on October 7, 2016 "ha[d] a \$120 million question attached to it," since Medicaid was projected to purchase \$120 million in EpiPens during a six-month grace period provided for under the alleged settlement agreement, and the details of the rebate terms governing those six months were not made public.<sup>54</sup>

552. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.24, or 3.24%, to close at \$37.07 on October 12, 2016.

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<sup>52</sup> Dan Mangan, *Underpayments on EpiPen rebates to Medicaid could top \$700 million*, *CNBC News* (Oct. 7, 2016), <http://www.cnn.com/2016/10/07/underpayments-on-epipen-rebates-to-medicaid-could-top-700-million-dollars.html>.

<sup>53</sup> Mylan N.V., Press Release, *Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector* (Oct. 7, 2016), <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector>.

<sup>54</sup> Dan Mangan, *Mylan's grace period for EpiPen rebates could cost Medicaid up to \$120 million*, *CNBC News* (Oct. 11, 2016), <http://www.cnn.com/2016/10/11/mylans-grace-period-for-epipen-rebates-could-cost-medicaid-up-to-120-million.html>.

**F. November 3, 2016**

553. On November 3, 2016, *Bloomberg News* reported that DOJ prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion.<sup>55</sup>

554. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$2.53, or 6.9%, to close at \$34.14 on November 3, 2016.

**G. November 10, 2016**

555. On November 10, 2016, reports emerged that an Evercore ISI analyst had estimated that Mylan could face liability of between \$380 million and \$770 million under the DOJ's price collusion investigation and that the DOJ could impose industry-wide fines in excess of \$1 billion.<sup>56</sup>

556. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price dropped \$0.64, or 1.64%, to close at \$38.28 on November 10, 2016.

**H. December 14, 2016**

557. On December 14, 2016, *Bloomberg News* reported that two executives, Jeffrey Glazer, ex-CEO and Chairman of Heritage, and Jason Malek, the former Senior Vice President of

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<sup>55</sup> David McLaughlin and Caroline Chen, *U.S. Charges in Generic-Drug Probe to Be Filed by Year-End*, *Bloomberg News* (Nov. 3, 2016), <https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end>.

<sup>56</sup> See, e.g., Eric Sagonowsky, *DOJ's price-fixing investigation could lead to sizable liabilities, analyst says*, *FiercePharma* (Nov. 10, 2016), <http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says>.

Commercial Operations for Heritage, were “preparing to plead guilty to price-fixing charges” in a scheme that involved unnamed executives from Mylan.<sup>57</sup>

558. On this news, the risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares dropped \$0.61, or 1.6%, to close at \$37.69 on December 14, 2016.

#### **I. January 10, 2017**

559. On January 10, 2017, *The Philadelphia Inquirer* reported that “Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company’s former senior vice president of commercial operations, admitted to conspiring to manipulate prices of a popular antibiotic and a diabetes medication between April 2013 and December 2015.”<sup>58</sup>

560. On this news, the risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result between January 10, 2017 and January 12, 2017, Mylan’s share price dropped \$2.18, or 5.6%, to close at \$36.77 on January 12, 2017.

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<sup>57</sup> Tom Schoenberg, David McLaughlin and Sophia Pearson, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, Bloomberg News, (Dec. 14, 2016), <https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe>.

<sup>58</sup> Jeremy Roebuck, *Ex-N.J. pharma execs admit to fixing generic drug prices*, Phil. Inquirer (Jan. 9, 2017), [http://www.philly.com/philly/news/new\\_jersey/20170110\\_Ex-N\\_J\\_pharma\\_execs\\_admit\\_to\\_fixing\\_generic\\_drug\\_prices.html](http://www.philly.com/philly/news/new_jersey/20170110_Ex-N_J_pharma_execs_admit_to_fixing_generic_drug_prices.html).

**J. January 30, 2017**

561. On January 30, 2017, *Bloomberg News* reported that Mylan had received a request for information from the FTC regarding whether Mylan had engaged in anticompetitive activity relating to the EpiPen.<sup>59</sup>

562. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$0.32, or 0.87% to close at \$36.34 on January 30, 2017.

**K. October 31, 2017**

563. On October 31, 2017, the Attorney General of the State of Connecticut issued a press release on behalf of 46 state attorneys general in which he announced that the group would be filing an amended complaint in their antitrust action against Mylan with a link to access the proposed amended complaint. The amended complaint contained extensive new allegations detailing how Mylan had participated in a wide-ranging price-fixing conspiracy and added Malik, Mylan's President and Executive Director, as an individual defendant for his direct participation in the conspiracy. The amended complaint also contained additional details regarding the conspiracy between Mylan and other drug companies to allocate the market for, and fix the prices of, generic drugs, and new allegations of express agreements between Mylan and other drug companies to fix the prices of additional generic drugs (*see* §VI, *supra*). The new allegations were based on an extensive investigation by the attorneys general, including the review of internal Mylan e-mails (many of which were cited and quoted in the allegations), telephone records, text messages, and other corporate documents.

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<sup>59</sup> David McLaughlin, Sara Forden and Jared Hopkins, *Mylan Faces U.S. Antitrust Investigation on EpiPen*, *Bloomberg News* (Jan. 30, 2017), <https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices>.

564. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$2.53, or 6.62%, to close at \$35.71 on October 31, 2017.

**L. May 13, 2019**

565. On May 10, 2019, after trading hours, the attorneys general of 44 states filed a lawsuit alleging extensive new allegations that Mylan and other generic drug companies had engaged in a massive conspiracy to allocate the market for, and fix the prices of, over 100 generic drugs. The complaint detailed compelling evidence, collected by the state attorneys general through an extensive investigation, that Mylan had conspired with competitors to allocate the markets for and fix the prices of numerous generic drugs. This evidence included details about the extensive communications between Mylan and its co-conspirators. The complaint made clear that Mylan and its co-conspirators' anticompetitive activity was not limited to a handful of drugs, but rather was so widespread as to be the standard procedure by which these companies operated in the marketplace: each company was entitled to its "fair share" of the market, and the companies agreed to "play nice in the sandbox."

566. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$2.09, or 9.43%, to close at \$20.08 on May 13, 2019.

**M. May 28, 2019**

567. On May 28, 2019, UBS published a report titled "Mylan Inc., Expanded Alleged price fixing creates another overhang – Reiterate Neutral; PT to \$23." In this report, UBS provided details regarding the potential exposure the Company faced in the 2017 and 2019 antitrust suits by the state attorneys general. Based on this analysis, UBS lowered its twelve-month price target from \$31.00 to \$23.00.

568. On this news, the risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.08, or 5.69%, to close at \$17.90 on May 28, 2019.

#### **IX. ADDITIONAL SCIENTER ALLEGATIONS**

569. Mylan, Bresch, Coury, Campbell, Malik, Parks, and Sheehan each knew about the false and misleading nature of the statements discussed above, or at a minimum were reckless for not knowing these matters.

570. During the Relevant Period, Coury and Bresch served successively as CEO of Mylan, Malik served as President, Sheehan and Parks served successively as CFO, and Campbell served as Chief Accounting Officer. Coury and Bresch, by virtue of their responsibilities and activities as CEO of the Company, Malik, by virtue of his responsibilities as President, Sheehan and Parks, by virtue of their responsibilities and activities as CFO, and Campbell, by virtue of his responsibilities and activities as the Company's Chief Accounting Officer, were privy to and participated in the fraudulent conduct described in this complaint.

571. Since Mylan's sales of the EpiPen accounted for a significant and material portion of its revenue and operating profits throughout the Relevant Period, Mylan's sales of the EpiPen were part of Mylan's core business. During the Relevant Period, the EpiPen was responsible for between 28% and 95% of Mylan's operating profits. Because Mylan's sales of the EpiPen were part of its core business, the Top Executives, and through them Mylan, would have had robust knowledge of significant aspects of those sales and knew about, or recklessly disregarded, Mylan's misclassification of the EpiPen for the purposes of the MDRP and Mylan's massive, unprecedented, and anticompetitive rebates to third-party payors expressly conditioned on their excluding Sanofi's Auvi-Q auto-injector from their formularies and Mylan's related conduct.

572. The Top Executives repeatedly attested to their robust knowledge of Mylan's sales and pricing activity. Each of Bresch, Coury, Parks, Sheehan, and Campbell signed certifications in Mylan's SEC filings pursuant to SOX in each quarter during which they held the roles of CEO, CFO or Chief Accounting Officer. In each of these certifications, these Top Executives each stated that the information contained in them was accurate and not misleading. These attestations required robust knowledge of Mylan's financial statements and the bases of these financial statements, including the bases for Mylan's statements of its sales, revenue, and drug pricing. These attestations also required robust knowledge of Mylan's statements of risk factors and whether those risks had materialized.

573. Bresch, Coury, Parks, Sheehan, and Campbell likewise repeatedly attested to their understanding of the rule for classifying drugs for the purposes of the MDRP and understood this rule to require products, like the EpiPen, that were marketed under NDAs to be classified as brand-name drugs. In SEC filings throughout the Relevant Period, each of Bresch, Coury, Parks, Sheehan, and Campbell certified that the following statement was accurate and not misleading:

The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

574. This statement makes clear that the Top Executives knew or recklessly disregarded the simple rule for the proper classification of the EpiPen for the purposes of the MDRP, knew the financial consequences of that classification for Medicaid and Mylan, and yet continued to classify the EpiPen as if it were marketed under an ANDA and subject to only a 13% rebate. The Top Executives each knew or recklessly disregarded that they were marketing their single most important drug, the EpiPen, as a brand-name drug under an NDA, rather than as a generic drug under an

ANDA, and so knew that under the simple rule they certified to be accurate and not misleading, the EpiPen was misclassified.

575. The Top Executives likewise knew or recklessly disregarded Mylan's misclassification of the EpiPen because CMS repeatedly informed Mylan that it was misclassifying the EpiPen for purposes of the MDRP and because, in November 2014, the DOJ had opened an investigation into "whether [the] EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs."

576. As stated above and in the Class Complaint, CW has confirmed that Coury and Bresch, as successive CEOs, and Sheehan and Parks, as successive CFOs, each knew of and approved all material pricing decisions made by the Company. CW started work at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW worked in Mylan's Morgantown, West Virginia facility, which at the time was the largest pharmaceutical manufacturing plant in the world. CW was part of several groups that met regularly to assess costs. In CW's role as Director of Costing, CW worked directly with CFO Sheehan. CW also attended company-wide meetings that were led by CEO Bresch and concerned Company initiatives. CW also worked with Mylan President Tony Mauro on costing decisions.

577. CW stated that pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives. "[Price] was always a topic." CW stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs. According to CW, Bresch and Coury both discussed price adjustments to Mylan's drugs frequently. "Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing." For



example, “[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at.” CW understood the “anthrax antibiotic” in question to be doxycycline.

578. The numerous investigations and legal actions into Mylan’s misclassification of the EpiPen and price fixing further evidence Mylan’s scienter. In addition to multiple, ongoing investigations by the DOJ, SEC, CMS, and U.S. Congress, the attorneys general of more than 40 states, in multiple investigations, have uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States by, among others, Mylan. Mylan senior executives participated consciously and willingly in the anticompetitive conduct at issue in these investigations.

579. That Mylan and the Top Executives knew about the Company’s market allocation and price-fixing activity alleged in this complaint is likewise clear because one of the executives at Mylan who directly participated in this activity, Nesta, Vice President of National Accounts at Mylan, was frequently in direct contact with the highest-level executives at the Company.

580. The information about Nesta’s position at Mylan from another former employee (“CW2”) was cited in the Class Complaint.

581. CW2 worked at Mylan from January 2004 to June 2007 as an Associate, Pricing and Contracts, and then from July 2007 to November 2017 as a Key Account Manager in the Dallas/Fort Worth area. CW2 last reported to Heather Paton, Mylan’s head of sales. During CW2’s tenure at Mylan, CW2 said CW2 attended meetings with Nesta. CW2 said that Nesta reported to Matthew Erick, who was President of North America at Mylan. Class Complaint, ¶590.

582. Nesta was, at all relevant times, a central player in Mylan’s market allocation and price-fixing scheme. He was very senior at Mylan – he reported to Matthew Erick, who was at all

relevant times President, North America for Mylan Pharmaceuticals. Matthew Erick reported directly to CEO Bresch. Accordingly, Nesta was only one reporting level removed from the CEO and was sufficiently senior at Mylan that his knowledge and actions may be imputed to the corporation. Class Complaint, ¶589.

583. Nesta routinely attended conferences with these highest level executives as part of a small group, which included the executives named below and Nesta. These conferences included at least the following:

- 2013 National Association of Chain Drug Stores (“NACDS”) Annual Meeting, attended with Mylan President Joe Duda and Chief Commercial Officer Tony Mauro;
- 2013 NACDS Total Store Expo, attended with Duda;
- 2014 Healthcare Distribution Management Association (“HDMA”) Sixth Annual CEO Roundtable Fundraiser, attended with Duda, Mauro, and COO Hal Korman;
- 2014 NACDS Annual Meeting, attended with Duda, Mauro, and Korman;
- 2015 HDMA Annual CEO Roundtable Fundraiser, attended with Mauro;
- 2015 HDMA Annual Board and membership meeting, attended with Mauro; and
- 2016 NACDS Annual Meeting, attended with Mauro.

584. That Mylan and Campbell and Parks agreed to settle the DOJ’s investigation into Mylan’s misclassification of the EpiPen for purposes of the MDRP for at least \$465 million evidences scienter.

585. That Mylan and the Top Executives knew or recklessly disregarded that Mylan offered massive, unprecedented rebates to third-party payors expressly conditioned on their not including Sanofi’s Auvi-Q in their formularies evidences scienter.

586. Mylan President Malik sold 25,000 shares of Mylan stock on June 9, 2017 (about 3% of his Mylan holdings) for proceeds of \$1 million, and Chief Commercial Officer Tony Mauro sold 10,000 shares of Mylan stock on June 9, 2017 (about 6.6% of his Mylan holdings) for proceeds of \$400,000. These sales evidence scienter.

587. That the prices of the Price-Fixed Drugs increased immediately following meetings of members of generic drug companies (attended by Mylan executives, including CEO Bresch) during which the companies, including Mylan, colluded to fix generic drug prices, evidences scienter.

#### **X. PRESUMPTION OF RELIANCE AND FRAUD-ON-THE-MARKET DOCTRINE**

588. There is a presumption of reliance established pursuant to the fraud-on-the-market doctrine because, among other things:

- (a) defendants made misrepresentations or omissions that were public;
- (b) the misrepresentations or omissions were material;
- (c) the misrepresentations or omissions would tend to induce a reasonable investor to misjudge the value of Mylan securities;
- (d) Mylan securities traded in an efficient market; and
- (e) Plaintiff traded in Mylan securities between the time the misrepresentations or omissions were made and the time the truth was revealed.

589. At all relevant times, the market for Mylan securities was efficient for the following reasons, among others:

- (a) Mylan shares met the requirements for listing and were listed and actively traded on the NASDAQ-GS, a highly efficient and automated market;
- (b) the average weekly trading volume of Mylan securities was significant;

(c) as a regulated issuer, Mylan filed public reports with the SEC and the NASDAQ-GS;

(d) Mylan was eligible to file simplified SEC filings;

(e) Mylan regularly communicated with the public through established market communication channels, including through the regular dissemination of news releases on major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(f) numerous securities and credit analysts followed Mylan and wrote reports that were published, distributed, and entered the public market.

590. As a result of the foregoing, the market for Mylan securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in their prices. All purchasers of Mylan securities during the Relevant Period suffered similar injury through their purchases of Mylan securities at artificially inflated prices and a presumption of reliance therefore applies.

591. In addition, or in the alternative, Plaintiff is entitled to a presumption of reliance pursuant to *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), and its progeny, because the claims asserted herein are predicated in part upon omissions of material fact that defendants had a duty to disclose.

## **XI. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR OR BESPEAKS CAUTION DOCTRINE**

592. The statutory safe harbor and bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the untrue or misleading statements alleged herein. First, the statements complained of herein concerned present or historical facts or conditions that were existing or purported to exist at the time they were made. Second, the

statutory safe harbor does not apply to statements included in financial statements that purport to have been prepared in accordance with GAAP. Further, to the extent that any of the untrue or misleading statements alleged herein were identified as forward looking, and can be construed as forward looking, the statements were not accompanied by meaningful cautionary statements identifying important facts that could cause actual results to differ materially from those statements, and the generalized disclosures made by defendants were not sufficient to shield them from liability.

593. In the alternative, to the extent the statutory safe harbor otherwise would apply, defendants are liable for any untrue or misleading forward-looking statement complained of herein because the person who made each such statement knew that the statement was false or misleading and/or each such statement was made or approved by an executive officer of the Company who knew that the statement was false or misleading.

## **XII. COUNT**

### **For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

594. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

595. This Count is asserted against all defendants for violations of §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

596. Defendants disseminated or approved the false and misleading statements specified above during the Relevant Period, which they knew, or deliberately disregarded, were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

597. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact

or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff in connection with its purchases of Mylan securities during the Relevant Period.

598. Defendants, directly or indirectly, by use of the means or instrumentalities of interstate commerce or of the mails, and by the use of the facilities of a national securities exchange with respect to Mylan securities, engaged in a continuous course of conduct that operated as a fraud and deceit, or otherwise used or employed manipulative or deceptive devices or contrivances, which were intended to and did: (i) deceive the investing public, including Plaintiff, regarding, among other things, Mylan's misclassification of the EpiPen to overcharge Medicaid by hundreds of millions of dollars and participation in illegal anticompetitive activities; (ii) artificially inflate and/or maintain the market price of Mylan securities; and (iii) cause Plaintiff to purchase Mylan securities at artificially inflated prices, and thereby suffer losses when the truth was revealed.

599. Defendants are liable for all materially false and misleading statements made during the Relevant Period, as alleged above.

600. As set forth above, defendants acted with the requisite scienter in that they acted either with intent to deceive, manipulate, or defraud, or with recklessness. The misrepresentations and omissions of material fact set forth herein, which presented a danger of misleading buyers or sellers of Mylan securities, were either known to defendants or were so obvious that defendants should have been aware of them.

601. Plaintiff suffered damages as a result of defendants' wrongful conduct in that Plaintiff purchased or otherwise acquired Mylan securities at artificially inflated prices in reliance on (i) defendants' untrue or misleading statements or omissions of material fact and/or (ii) the integrity of

the market. Plaintiff would not have purchased or otherwise acquired Mylan securities at the prices it paid, or at all, had it been aware that those prices were artificially inflated and/or maintained as a result of the wrongful conduct alleged herein.

602. As a direct and proximate result of defendants' wrongful conduct, Plaintiff suffered damages attributable to the material misstatements and omissions alleged herein in connection with its purchases of Mylan securities during the Relevant Period.

### **XIII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully prays for relief and judgment as follows:

A. Declaring and determining that defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

B. Awarding Plaintiff compensatory damages against all defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

C. Awarding Plaintiff reasonable costs and expenses incurred in this action, including but not limited to attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

D. Granting such other and further relief as the Court deems just and proper.

### **XIV. JURY DEMAND**

Plaintiff hereby demands a trial by jury.

DATED: February 14, 2020

ROBBINS GELLER RUDMAN  
& DOWD LLP  
SAMUEL H. RUDMAN

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*/s/ Samuel H. Rudman*  
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